No. 92-102-CFX
Status: GRANTED

Title: William Daubert, et ux., etc., et al., Petitioners
v.
Merrell Dow Pharmaceuticals, Inc.

Docketed:
July 7, 1992

Court: United States Court of Appeals for
the Ninth Circuit

Counsel for petitioner: Chesebro,Kenneth J.

Counsel for respondent: Dickson,Robert L., Fried,Charles

NOTE: See mail label rec'd 071592

Entry	Date	Note	Proceedings and Orders
1	Jul 7 1992	G	Petition for writ of certiorari filed.
2	Aug 7 1992		Brief of respondent Merrell Dow Pharmaceuticals in opposition filed.
3	Aug 12 1992		DISTRIBUTED. September 28, 1992
4	Aug 25 1992	X	Reply brief of petitioner William Daubert, et ux. filed.
7	Oct 5 1992		REDISTRIBUTED. October 9, 1992
8	Oct 13 1992		Petition GRANTED.
			**********
10	Nov 16 1992		Order extending time to file brief of petitioner on the merits until December 2, 1992.
11	Dec 2 1992		Brief amicus curiae of American Law Professors filed.
12	Dec 2 1992		Brief amicus curiae of Carnegie Commission on Science, Technology, & Government filed.
13	Dec 2 1992		Joint appendix filed.
14	Dec 2 1992		Brief amicus curiae of Physicians, Scientists, and Historians of Science filed.
15	Dec 2 1992		Brief amici curiae of Professors Kenneth Rothman, et al. filed.
16	Dec 2 1992		Brief amici curiae of Texas, et al. filed.
17	Dec 2 1992		Brief amicus curiae of Association of Trial Lawyers of America filed.
18	Dec 2 1992		Brief amici curiae of American Society of Law, Medicine and Ethics, et al. filed.
19	Dec 2 1992		Brief of petitioners William Daubert, et ux., et al. filed.
20	Dec 2 1992		Brief amici curiae of Daryl E. Chubin, et al. filed.
22	Dec 16 1992		Order extending time to file brief of respondent on the merits until January 19, 1993.
23	Jan 19 1993		Brief of respondent Merrell Dow Pharmaceuticals, Inc. filed.
24	Jan 19 1993		Brief amicus curiae of Washington Legal Foundation filed.
25	Jan 19 1993		Brief amicus curiae of Chamber of Commerce of the United States of America filed.
26	Jan 19 1993		Brief amicus curiae of American Tort Reform Association filed.
27	Jan 19 1993		Brief amici curiae of American Association for the Advancement of Science, et al. filed.
28	Jan 19 1993		Brief amicus curiae of Pharmaceutical Manufacturers Association filed.
29	Jan 19 1993		Brief amicus curiae of American Insurance Association filed.
30	Jan 19 1993		Brief amicus curiae of Alvan R. Feinstein filed.
31	Jan 19 1993		Brief amici curiae of American Medical Association, et al.

No. 92-102-CFX

Entry	Date	Note	Proceedings and Orders
			filed.
32	Jan 19 1993		Brief amici curiae of Nicolaas Bloembergen, et al. filed.
33	Jan 19 1993		Brief amici curiae of New England Journal of Medicine, et al. filed.
34	Jan 19 1993		Brief amici curiae of Product Liability Advisory Council, et al. filed.
35	Jan 19 1993		Brief amicus curiae of Defense Research Institute, Inc. filed.
36	Jan 19 1993		Brief amicus curiae of American College of Legal Medicine filed.
37	Jan 19 1993		Brief amicus curiae of United States filed.
38	Jan 21 1993	D	Motion of American College of Legal Medicine for leave to participate in oral argument as amicus curiae, for divided argument and for additional time for oral argument filed.
40	Feb 4 1993		CIRCULATED.
41	Feb 4 1993	D	Application (A92-593) extension of time to file reply brief on the merits, submitted to Justice O'Connor.
42	Feb 8 1993		Application (A92-593) denied by Justice O'Connor.
43	Feb 22 1993		Motion of American College of Legal Medicine for leave to participate in oral argument as amicus curiae, for divided argument and for additional time for oral argument DENIED.
44	Feb 22 1993	X	Reply brief of petitioners filed.
39	Mar 3 1993		SET FOR ARGUMENT TUESDAY, MARCH 30, 1993. (1ST CASE).
45	Mar 11 1993		Record filed.
		*	Partial proceedings United States Court of Appeals for the Ninth Circuit.
46	Mar 12 1993		Record filed.
		*	Certified proceedings United States District Court for the Southern District of California (2 Boxes)
47	Mar 30 1993		ARGUED.

Supreme Court, U.S.
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92-102
No. 92-

IN THE
Supreme Court of the United States
October Term, 1992

WILLIAM DAUBERT AND JOYCE DAUBERT, INDIVIDUALLY AND AS GUARDIANS AD LITEM FOR JASON DAUBERT, AND ANITA DE YOUNG, INDIVIDUALLY AND AS GUARDIAN AD LITEM FOR ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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July 7, 1992

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QUESTIONS PRESENTED

1. Whether the uniform Federal Rules of Evidence enacted by Congress in 1975 eliminated the judge-made "general acceptance" test of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), as a ground for excluding scientific evidence.

2. Whether the lower federal courts possess inherent judicial power to create their own rules for excluding evidence which: (a) exceed those enumerated by Congress in Fed. R. Evid. 402, (b) bypass the procedural safeguards for evidence rulemaking mandated by Congress in 28 U.S.C. §§ 2071-2077, and (c) effect substantive revision of rights granted parties under state tort law.

3. Whether the lower federal courts may constitutionally delegate control over the admissibility of scientific expert opinion testimony to the editors of peer-reviewed journals, on the ground that these editors are "the recognized authorities in the field," and that such delegation is necessary to ensure that "those most qualified to assess the general validity of a scientific method will have the determinative voice."

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Ninth Circuit, affirming the district court's grant of summary judgment for respondents, is reported at 951 F.2d 1128, and is reprinted as Appendix A, at page A1. (References to the appendices bound with this Petition are styled "A___".) The memorandum decision and order of the United States District Court for the Southern District of California, from which appeal was taken, is reported at 727 F. Supp. 570, and is reprinted as Appendix B, at page A6.

JURISDICTION

The decision of the Court of Appeals was announced on December 20, 1991. A timely petition for rehearing and suggestion for rehearing *en banc* was denied on April 8, 1992. See Appendix C, at page A16. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED

The Federal Rules of Evidence were enacted by Congress as a statute in 1975, Pub. L. No. 93-595, 88 Stat. 1926 (1975), 28 U.S.C app. (1988). Rule 402 provides:

Rule 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible

All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Rule 702 of the Federal Rules of Evidence provides:

Rule 702. Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

28 U.S.C. § 2071 (1988) provides, in relevant part:

§ 2071. Rule-making power generally

(a) The Supreme Court and all courts established by Act of Congress may from time to time prescribe rules for the conduct of their business. Such rules shall be consistent with Acts of Congress and rules of practice and procedure prescribed under section 2072 of this title.

(b) Any rule prescribed by a court, other than the Supreme Court, under subsection (a) shall be prescribed only after giving appropriate public notice and an opportunity for comment. Such rule shall take effect upon the date specified by the prescribing court and shall have such effect on pending proceedings as the prescribing court may order.

28 U.S.C. § 2072 (1988) provides, in relevant part:

§ 2072. Rules of procedure and evidence; power to prescribe.

(a) The Supreme Court shall have the power to prescribe general rules of practice and procedure and rules of evidence for cases in the United States district courts (including proceedings before magistrates thereof) and courts of appeals.

(b) Such rules shall not abridge, enlarge or modify any substantive right. All laws in conflict with such rules shall be of no further force and effect after such rules have taken effect.

The Rules of Decision Act, 28 U.S.C. § 1652 (1988) provides, in relevant part:

§ 1652. State laws as rules of decision.

The laws of the several states, except where the Constitution or treaties of the United States or Acts of Congress otherwise require or provide, shall be regarded as rules of decision in civil actions in the courts of the United States, in cases where they apply.

The Seventh Amendment to the United States Constitution provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

STATEMENT OF THE CASE

1. This is a products liability case falling under diversity jurisdiction and governed by California law. The facts leading to the lawsuit are not disputed. Minor petitioners Jason Daubert and Eric Schuller were born with severe and permanent limb-reduction birth defects. Their parents, also petitioners in this Court, filed suit in California state court against respondent Merrell Dow Pharmaceuticals, Inc. ("Merrell"), alleging that the birth defects had been caused by Bendectin, a prescription anti-nausea drug marketed by Merrell. Each of the children's mothers had taken Bendectin during the limb-development phase of pregnancy, and no other identifiable risk factor was present. Eight experts put forward their testimony in support of the petitioners' allegation that Bendectin had caused both sets of limb defects. (A11.) Merrell elected to remove the cases, given the diversity of citizenship, to the United States District Court for the Southern District of California.

2. After preliminary discovery, Merrell moved for summary judgment in the district court on the issue of causation. In its filing under Fed. R. Civ. P. 56(e), Merrell claimed that there exists no scientific proof that Bendectin causes birth defects, and therefore that it could not have caused the birth defects at issue in the case. The sole admissible evidence introduced by Merrell in support of this proposition consisted of the conclusion of one expert witness, whom petitioners conceded was qualified to state an opinion concerning the effect of Bendectin on birth defects. Dr. Steven H. Lamm, a pediatrician, stated in a two-page affidavit that he had read all epidemiological data collected and published in medical and scientific journals which related to

estimating the effect of Bendectin on mass populations. Dr. Lamm then stated:

> Based on my review of the scientific literature, I conclude that maternal use of Bendectin during the first trimester of pregnancy is not a risk factor for human birth defects in general, for limb reduction defects specifically, or for any other particular human birth defect.

Aff. dated August 1, 1989, at 2.

This ultimate statement of opinion, standing alone, constituted admissible evidence, because Rules 704(a) and 705 of the Federal Rules of Evidence permit qualified experts to state their opinions on an ultimate issue of fact without disclosing the facts or data underlying their opinions. Dr. Lamm did provide several paragraphs of elaboration about the sorts of inquiries into the available epidemiological data that had led him to his ultimate opinion that Bendectin use is not a risk factor. But neither the underlying data nor detail about those inquiries was entered into evidence. They were not part of the admissible summary judgment record at all, but simply served to enhance the credibility of Dr. Lamm's opinion. Dr. Lamm freely and informally referred to these outside sources as permitted by Rule 703 of the Federal Rules of Evidence, which (as the Ninth Circuit has expressly agreed with other circuits) functions as "the expert testimony exception to the hearsay rules." *United States v. Unruh*, 855 F.2d 1363, 1376 (9th Cir. 1987), *cert. denied*, 488 U.S. 974 (1988).[1]

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[1] *See also Rogers v. Raymark Industries, Inc.*, 922 F.2d 1426, 1429-30 (9th Cir. 1991) ("an expert opinion may be based on any type of evidence commonly used in the field"); *United States v. Lundy*, 809 F.2d 392, 395-96 (7th Cir. 1987) ("hearsay and third-party observations that are of a type normally relied upon by an expert in the field are properly utilized by such an expert in developing an expert opinion"); *Mannino v. International Manufacturing Co.*, 650 F.2d 846, 851 (6th Cir. 1981) ("[t]he purpose of Rule 703 is to make available to the expert all of the kinds of things that an expert would normally rely upon in forming an opinion, without requiring that these be admissible in evidence"; through it "the law is catching up with the realities of professional life"); *Clinchfield R.R. Co. v. Lynch*, 784 F.2d 545, 553-544 (4th Cir. 1986) (on Rule 703 showing that data are "regularly relied upon" by experts in field, questions going to weight should be "'attacked by cross examination and refutation'").

As required by Fed. R. Civ. P. 56(e), petitioners opposed summary judgment with affidavits from expert witnesses, skilled in several relevant scientific and medical disciplines. Merrell readily conceded that each of the eight experts was qualified to state an opinion concerning the effect of Bendectin on birth defects. One of petitioners' experts, Dr. John Palmer, a medical professor and physician specializing in pharmacology, concluded:

> I have also examined the medical records pertaining to the Daubert and Schuller children and it is my opinion within a reasonable degree of medical certainty that in each case the drug Bendectin was taken at the period of time so as to [affect] the cells that would produce the normal limb structure and that Bendectin did cause the limb defects in each of the children.

Aff. dated Sept. 22, 1989, at ¶ 14. Under Fed. R. Evid. 704(a) and 705, this ultimate statement of opinion about causation from a qualified expert, standing alone, was sufficient to serve as admissible proof of causation.

The credibility of Dr. Palmer's opinion was enhanced, however, by several pages of elaboration on his reasoning and on his consideration of data from four standard sources of information about whether particular substances cause birth defects: (1) *in vitro* animal tests on animal cells, (2) *in vivo* animal tests on live animals, (3) analysis of chemical structure, and (4) analysis of data contained in the same published epidemiological studies considered by Merrell's experts. As with the sources of data relied on by Merrell's contrary expert, the sources relied on by Dr. Palmer were not themselves entered into evidence. Rather, Dr. Palmer referred to these outside sources pursuant to Fed. R. Evid. 703. Petitioners also submitted the affidavits of seven other concededly qualified experts drawn from a variety of fields related to birth defects, including teratology (the study of substances that produce malformations in human fetuses), pathology, chemistry, developmental biology, pharmacology, toxicology, embryology, dysmorphology and epidemiology. These seven affidavits demonstrated to the district court the evidence petitioners proposed to offer in order to enhance the credibility of Dr. Palmer's ultimate opinion at trial. (*See* A11-A13 (summarizing proffered testimony.))

3. The district court granted summary judgment on the basis that none of petitioners' expert testimony was admissible, "because it lacks the sufficient foundation necessary under FRE 703." In doing so, the district court cited decisions rendered by the D.C. Circuit and the First Circuit in Bendectin cases involving different plaintiffs and different evidence. *See* note 2, *infra*. The cases cited by the district court utilized Rule 703 to uphold exclusion of plaintiffs' expert causation testimony on the basis that either: (1) the testimony excluded epidemiological data; or (2) the testimony included epidemiological data but plaintiffs' expert did not cite a specific, published, peer-reviewed study which, considered in isolation, proves causation with "statistical significance," i.e., 95 percent certainty. (A8-A10, A13-A15.)[2]

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[2] As the district court summarized its holding: "The federal courts have held that epidemiological studies are the most reliable evidence of causation in this area. Accordingly, expert opinion which is not based on epidemiological evidence is not admissible to establish causation because it lacks the sufficient foundation necessary under FRE 703. Therefore, expert testimony concluding that Bendectin causes limb reduction defects which is generally based upon *in vitro* studies, chemical structure analyses and animal studies is insufficient to take the issue to the jury. The plaintiffs' experts must be competent to testify that some epidemiological study or recalculation shows a statistically significant relationship between the ingestion of Bendectin and birth defects and that this study forms the basis of their opinion." (A13-A14 (citing *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990) (sufficiency-of-evidence holding); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989) (Rule 703 holding); *Lynch v. Merrell--National Labs.*, 830 F.2d 1190 (1st Cir. 1987) (Rule 703 holding).)

The district court added: "The defendants have introduced evidence that no epidemiological study ever performed has concluded that the use of Bendectin by pregnant woman has a statistically significant association to birth defects in those women's children. . . . The plaintiffs argue that the absence of statistically significant epidemiological studies does not disprove the fact that Bendectin causes limb reduction defects. However, this argument directly contradicts the holdings of *Brock*, *Richardson* and *Lynch*. The plaintiffs have the burden of proof, and they must come forward with statistically significant epidemiological evidence. The plaintiffs claim that Dr. Gross performed a new epidemiological study on Bendectin, but this is false. He simply recalculated a previously published study and tried to show that there actually was a significant relation between Bendectin and birth defects. Dr. Gross' 'study' was apparently never published or subjected to peer review, and nowhere does it state that Bendectin sales increased the relative risk of limb reduction defects to a level significantly above 1.0 with a confidence interval that did not include unity. Dr. Gross alleges that this 'study' shows 'a statistically significant association that is highly significant,' but his allegation and this evidence is insufficient to take this matter to a jury. Similarly, Dr. Swan's unsupported allegation that the Jick data 'statistically significantly associates Bendectin and limb defects' is similarly insufficient." (A14-A15 (citations omitted).)

4. On appeal in the Ninth Circuit, petitioners attacked the district court's exclusion of their expert testimony under Rule 703, arguing among other things that the legal construction of Rule 703 borrowed by the district court from the two other circuits was incorrect. Petitioners argued that this construction conflicted with the Third Circuit's recent decision in *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990), and with established Ninth Circuit precedent, *see* page 4 & note 1, *supra*.

The Ninth Circuit below, affirming the district court's grant of summary judgment, declined to review these legal arguments concerning Rule 703. Instead, it advanced its own ground for excluding petitioners' expert testimony -- the judge-made "*Frye* rule" -- and held that the exclusion of all of petitioners' expert testimony was proper because that testimony had failed to meet the strictures of *Frye*. As the Ninth Circuit explained the rule:

> Expert opinion based on a scientific technique "is admissible if it is generally accepted as a reliable technique among the scientific community." *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985) (citing *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923)). We impose this requirement because such evidence "creates a substantial danger of undue prejudice or of confusing the issues or of misleading the jury . . . because of its aura of special reliability and trustworthiness." *United States v. Amarel*, 488 F.2d 1148, 1152 (9th Cir. 1973); *see also* Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 HARV.L.REV. 40, 50-52 (1901).
>
> * * *

> For expert opinion based on a given scientific methodology to be admissible, the methodology cannot diverge significantly from the procedures accepted by recognized authorities in the field. If it does so diverge, it cannot be shown to be "generally accepted as a reliable technique," *Solomon*, 753 F.2d at 1526, and a district court must exclude it.

(A2-A3.)

The "methodology" that the Ninth Circuit found problematic under the *Frye* test was what the court called "the reanalysis methodology employed by plaintiffs' experts" in analyzing the epidemiological data contained in published studies. (A5.) Rather than restating the published *conclusion* of each epidemiological study, plaintiffs' experts looked at the *underlying data* in the studies, applied less stringent certainty standards, and pooled data from various studies to minimize the effect of random variation affecting any one study. By so doing, plaintiffs' experts were able to offer an opinion contrary to that of the original authors of the studies. That is, through careful analysis of the original data in each study juxtaposed by consideration of the data in other studies, plaintiffs' experts were able to disagree with the original authors and conclude that the data on balance provided substantial evidence of causation. The Ninth Circuit did not rule against the legitimacy of this "reanalysis methodology." Rather, the court found *Frye* unsatisfied simply because plaintiffs' experts had not published their conclusions in peer-reviewed journals before submitting their affidavits in court:

> Plaintiffs argue that reanalysis is a generally accepted scientific technique, so it follows that their experts were basing their opinions on a permissible methodology. But the reanalysis of epidemiological studies is generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field. Plaintiffs' reanalyses do not comply with this standard; they were unpublished, not subjected to the normal peer review process, and generated solely for use in litigation. It does not suffice that the expert's methodology meet *some* of the requirements imposed by the scientific community; it must meet *all* of the essential requirements. Selective borrowing from generally accepted scientific methodology does not satisfy *Solomon*'s rigorous standard.

(A4-A5 (citation and footnote omitted; emphasis in original).)

The Ninth Circuit's reasoning was in accord with the philosophy of restrictive admissibility underlying the *Frye* rule, as expressed by the D.C. Circuit which invented it, *see* pp. 22-23, *infra*:

> [T]he *Frye* standard retards somewhat the admission of proof based on new methods of scientific investigation by requiring that they attain sufficient currency and status to gain the general acceptance of the relevant scientific community. This is not to say, however, that the *Frye* standard exacts an unwarranted cost. The requirement of general acceptance in the scientific community assures that those most qualified to assess the general validity of a scientific method will have the determinative voice.

United States v. Addison, 498 F.2d 741, 743-44 (D.C. Cir. 1974) (footnotes omitted). The Ninth Circuit candidly recognized, however, that use of the judge-made *Frye* rule is not a universal practice, as revealed by the Third Circuit's decision in *DeLuca*. Reviewing that decision, the Ninth Circuit expressly noted the conflict between its holding and the Third Circuit's position:

> Because the Third Circuit has specifically rejected the *Frye/Solomon* 'generally accepted' standard, *United States v. Downing*, 753 F.2d 1224, 1236-37 (3d Cir. 1985), we find the court's analysis in *DeLuca* to be contrary to our established precedent and decline to follow it.

(A4 n.2.)

REASONS FOR GRANTING THE WRIT

1. This Court Should Resolve the Interminable Circuit Conflict Over Whether the Judge-Made *Frye* Rule Has Survived the Enactment of the Federal Rules of Evidence

This is the third case before this Court in recent months presenting an issue on which the lower federal courts have been unable to agree: whether the judge-made rule of *Frye v. United*

States, 293 F. 1013 (D.C. Cir. 1923), was eliminated as a ground for excluding evidence by Congress's enactment of uniform Federal Rules of Evidence. The *Frye* rule was designed to withhold novel but otherwise admissible scientific evidence from juries until the underlying methodologies gain "general acceptance" among scientists in the field, and the continued vitality of this rule is an issue that has long divided the circuits.

As early as 1986, two Justices of this Court noted a split among three circuits over the status of *Frye*. *See United States v. Mustafa*, 22 M.J. 165 (C.M.A.), *cert. denied*, 479 U.S. 953 (1986) (White, J., joined by Brennan, J., dissenting) (recommending grant of certiorari "to resolve this conflict on an obviously recurring and important issue"). Today, at least six circuits (including the Ninth Circuit below) hold that judicial use of *Frye* is allowable under the Federal Rules of Evidence.[3] By contrast, three other circuits have held that the *Frye* test is incompatible with the expert testimony provisions because

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[3] The other five circuits are:

Fifth Circuit: *Christophersen v. Allied Signal Corp.*, 939 F.2d 1106, 1115-16 (5th Cir. 1991) (per curiam), *cert. denied*, 112 S. Ct. 1280 (1991). *See* pp. 11-13, 17 & n.5, *infra*.

Sixth Circuit: *United States v. Metzger*, 778 F.2d 1195, 1203 (6th Cir. 1985), *cert. denied*, 477 U.S. 906 (1986) (stating that "[a]lthough '[a] number of the federal courts have responded to the enactment of Rule 702 by rejecting the *Frye* standard, [this circuit] still predicate[s] the admission of scientific evidence on general acceptance in the community'") (quoting academic commentary).

Seventh Circuit: *United States v. Smith*, 869 F.2d 348, 351 (7th Cir. 1989) (stating that "[a]lthough the validity of the judge-made rule in *Frye* has been criticized by some courts and commentators for numerous reasons, this circuit has continued to affirm (and to apply) the *Frye* standard").

Eighth Circuit: *United States v. Two Bulls*, 918 F.2d 56, 60 & n.7 (8th Cir. 1990) (refusing to reject use of *Frye* in evaluation of "the admissibility of any questionable opinion evidence").

D.C. Circuit: *United States v. Shorter*, 809 F.2d 54, 59-61 (D.C. Cir.), *cert. denied*, 484 U.S. 817 (1987) (reaffirming that "*Frye* is still the law of this Circuit").

Congress designed the Rules to override judge-made restrictions on expert testimony, leaving juries responsible for evaluating possible weaknesses in scientific and other expert testimony in both criminal and civil cases.[4]

In March, 1992, this Court was faced with the *Frye* issue in a petition seeking review of a bitter 8-to-5 split within the *en banc* Fifth Circuit in a diversity case, *Christophersen v. Allied Signal Corp.*, 939 F.2d 1106 (5th Cir. 1991) (per curiam), *cert. denied*, 112 S. Ct. 1280 (1991). *See* Petition for Certiorari, No. 91-785. In his Fifth Circuit concurrence in the result of that case, Chief Judge Clark vigorously opposed any use of *Frye*: "[I]f *Frye* is a rule of evidence, it has not survived the enactment of the Federal Rules of Evidence. . . . [I]f it is a substantive rule, its adoption in diversity cases is foreclosed by *Erie*." 939 F.2d at 1120 (Clark, J., concurring in the result) (citations omitted). Chief Judge Clark also "completely agree[d]," *ibid.*, with the views of four dissenters in that case that the Fifth

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[4] In one of the earliest decisions to move away from *Frye*, the Fourth Circuit commented: "Unless an exaggerated popular opinion of the accuracy of a particular technique makes its use prejudicial or likely to mislead the jury, it is better to admit relevant scientific evidence in the same manner as other expert testimony and allow its weight to be attacked by cross-examination and refutation." *United States v. Baller*, 519 F.2d 463, 466 (4th Cir.), *cert. denied*, 423 U.S. 1019 (1975).

The Third Circuit, in *United States v. Downing*, 753 F.2d 1224, 1232-37 (3rd Cir. 1985), surveyed the history of *Frye* and of the academic and judicial commentary, summarized *Frye*'s "serious flaws" -- notably "its vagueness and its conservatism" -- and concluded that *Frye* "should be rejected as an independent controlling standard of admissibility" because it "reflects a conservative approach to the admissibility of scientific evidence that is at odds with the spirit, if not the precise language, of the Federal Rules of Evidence." *Id.* at 1236-37. The Third Circuit reaffirmed its rejection of *Frye* in *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 955 (3d Cir. 1990) (the precedent noted by the Ninth Circuit below, *see* A4 n.2), stating: "We [explicitly rejected *Frye* in *Downing*], for among other reasons, because the general acceptance test was too vague and malleable to yield consistent results, and because its nose-counting emphasis often led to the exclusion of helpful evidence in contradiction to the spirit of the Federal Rules of Evidence." *Id.* at 955.

The Second Circuit recently rejected any use of *Frye* in *United States v. Jakobetz*, 955 F.2d 786, 794-97 (2d Cir. 1992). *See* pages 13-16, *infra*.

Circuit was vastly expanding the scope of the *Frye*, without authority in this Court's precedents and directly contrary to this Court's jurisprudence under *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938). *See* 939 F.2d at 1132-33 & n.41, 1134-36 & n.48 (Reavley, J., dissenting). Nevertheless, the *en banc* majority in *Christophersen* relied on *Frye* to uphold exclusion of an expert opinion. 939 F.2d at 1115-16.

Despite *Christophersen*'s fervent *en banc* debate over the legitimacy of applying *Frye* as a rule for excluding evidence, especially in diversity cases, *Christophersen* did not prove to be a suitable vehicle for certiorari on the issue, for at least two reasons. First, the Opposition to Certiorari in *Christophersen* stressed that "for the Court to reach the *Frye* issue in this case, it must first consider and hold" for petitioners on other, fact-bound evidentiary issues; the Opposition therefore urged this Court to deny review and wait for "a case in which the *Frye* issue will be necessarily and directly addressed." Opp. at 8-9. Second, the Opposition noted that a Judicial Conference committee was then seriously considering a major revision to Fed. R. Evid. 702 designed to "allow courts to 'reject testimony that is based upon premises lacking any significant support and acceptance within the scientific community, or that otherwise would be only marginally helpful to the fact-finder.'" Opp. at 8 (quoting commentary to proposed revision). *See also Federal Rules: Major Changes Sought By Judicial Conference Working Group*, 60 U.S.L.W. 2158 (1991), at 2158. The Opposition, at 8, argued that adoption of this codification of the *Frye* principle would "eliminate any precedential value of this case" and that a grant of certiorari would therefore be premature.

Ultimately, this Court denied review in *Christophersen*. 112 S. Ct. 1280 (March 2, 1992). Nevertheless, two Justices sketched the current circuit conflict over *Frye* and urged review of the issue. *Id.* at 1281 (White, J., joined by Blackmun, J., dissenting) (observing that "the appropriate standard for determining the admissibility of expert testimony . . . is an issue that has long divided the federal courts and here deeply divided the Court of Appeals for the Fifth Circuit, sitting *en banc*. . . . Because this is an important and recurring issue, I would grant certiorari to resolve the conflict.") (citation omitted).

The proposed revision to Fed. R. Evid. 702 encountered substantial opposition and subsequent to this Court's denial of review in *Christophersen*, on June 20, 1992, the Standing Committee in charge of revisions declined, by a 7-to-4 vote, to advance the proposal to the Judicial Conference for further consideration. *See* BNA Daily Report for Executives, June 23, 1992 (available on NEXIS, 1992 DER 121 d31).

Although *Christophersen* was unsuitable for this Court's resolution of the *Frye* conflict, two petitions for certiorari (including this petition) that necessarily and directly address the *Frye* issue are presently pending before this Court. Both cases were mentioned as part of the description of the circuit conflict in the *Christophersen* dissent from denial of certiorari. *See* 112 S. Ct. at 1281 (White, J., joined by Blackmun, J., dissenting).

The petition in case No. 91-7921, *Jakobetz v. United States*, a criminal case, seeks review of the Second Circuit's refusal to follow other circuits in requiring prosecutors to meet *Frye*'s heightened standard for admissibility when seeking to introduce new forms of forensic evidence. *See* note 3, *supra* (listing circuits); page 23-24, *infra* (sketching prosecutorial burden). In *Jakobetz* the Second Circuit rejected a criminal defendant's claim that prosecutors should have been forced to prove that the "DNA fingerprinting" evidence used against him enjoyed "general acceptance" in the field. In the process the Second Circuit reaffirmed its early abandonment of the *Frye* rule and, in particular, rejected the Eighth Circuit's application of *Frye* to DNA fingerprinting. *United States v. Jakobetz*, 955 F.2d 786, 794-97 (2d Cir. 1992).

Jakobetz reviewed a district court's decision to admit testimony based on the new technique of "DNA fingerprinting," first introduced in 1988, which relies on person-to-person differences in DNA and which "has been widely hailed as a revolutionary forensic tool that takes some of the uncertainty [as to identity] out of criminal convictions." Gina Kolata, *Critic of "Genetic Fingerprint" Test Tells of Pressure to Withdraw Paper*, N.Y. Times, Dec. 20, 1991, at A20, col. 4. Recent public criticisms by some scientists of the reliability of DNA fingerprinting have raised alarm in the law enforcement community, since under *Frye* "DNA evidence cannot be admitted in evidence

unless the [government] establishes that there is a *consensus* among scientists that it is valid." *Ibid.* (emphasis added). Some state courts and the Eighth Circuit have relied on *Frye* to limit sharply the use of DNA evidence, given the absence of such scientific consensus. *See, e.g., Fight Erupts Over DNA Fingerprinting*, 254 Science 1721 (Dec. 20, 1991); Rorie Sherman, *DNA Evidence Dispute Escalates*, Nat'l L.J., Jan. 20, 1992, at 3, col. 1; Gina Kolata, *Chief Says Panel Backs Courts' Use of a Genetic Test*, N.Y. Times, Dec. 20, 1991, at A1, col. 1.

The Second Circuit avoided all these difficulties by reaffirming an earlier ruling that *Frye* has no place in the Federal Rules of Evidence. The defendant's arguments for use of *Frye*, the Second Circuit noted, asserted a "very real danger that the critical faculties" of lay jurors can be "overwhelmed by the highly technical features of forensic DNA testing" and an inability of the jury to "independently and critically scrutinize technical DNA evidence when confronted by the testimony of experts," which can create an "'aura of mystic infallibility.'" 955 F.2d at 796. The Second Circuit rejected these elitist arguments for using the *Frye* rule or any other "general acceptance" rubric, holding: "Although we realize that DNA evidence does present special challenges, we do not think that they are so special as to require a new standard of admissibility. Despite the difficulties involved in cases with novel, complex and confusing evidence, the jury must retain its fact-finding function." *Id.* at 796. The court "agree[d] with both Professor McCormick and Judge Weinstein" that continued use of the restrictive *Frye* rule is inconsistent with the Federal Rules of Evidence. *Id.* at 797. The Second Circuit also expressly rejected the extremely stringent *Frye* test applied to DNA fingerprinting by the Eighth Circuit in *United States v. Two Bulls*, 918 F.2d 56 (8th Cir. 1990), in which the Eighth Circuit denied the government's request for a holding that the Federal Rules of Evidence supersede *Frye*. *Id.* at 795-96. The Ninth Circuit's decision below embraced the same "aura of mystic infallibility" justification for the *Frye* test that the Second Circuit rejected, as the Ninth Circuit expressed its concern about the "'aura of special reliability and trustworthiness'" supposedly surrounding expert testimony. (A2.)

The *Jakobetz* petition No. 91-7921 asks this Court to resolve

this Second Circuit-Eighth Circuit conflict over the treatment of DNA evidence and more generally, with reference to *Frye*, emphasizes that "[t]he circuits are divided over the issue of what standards to employ in determining the admissibility of novel scientific evidence in general." Petition at 15 (citations omitted). In his response to this petition, the Solicitor General has frankly agreed that there is a deep circuit conflict over the *Frye* issue presumably worthy of this Court's review, and he has furnished a succinct and neutral summary of that circuit conflict:

> Petitioner contends (Pet. 13-18) that there is a conflict among the courts of appeals regarding the correct standard for determining the admissibility of evidence based on novel scientific techniques . . . . As petitioner correctly notes (Pet. 15), the courts of appeals are divided as to the correct standard for determining the admissibility of expert testimony based on novel scientific evidence. The admissibility of such testimony in federal court is governed by Fed. R. Evid. 702, which permits "a witness qualified as an expert by knowledge, skill, experience, training or education" to testify concerning "scientific, technical, or other specialized knowledge" if the testimony "will assist the trier of fact to understand the evidence or to determine a fact in issue." Some courts of appeals have decided that admissibility of novel scientific evidence under Rule 702 should turn on its relevance and materiality and on whether it will assist the jury to resolve factual issues at trial, not exclusively on the degree to which it has gained general acceptance in the scientific community. . . . Other courts of appeals have continued to apply the threshold test first articulated in *Frye*, in which the court held that expert testimony based on novel scientific theories or discoveries is admissible only if there has been a preliminary showing that the theory or discovery is "sufficiently established to have gained general acceptance in the particular field in which it belongs."

Brief for the United States in Opposition, No. 91-7921, filed June 10, 1992, at 8-10 (extensive citations omitted).

The Solicitor General's opposition to review in *Jakobetz* flowed not from doubt about the importance of the circuit conflict thus presented but instead from concern about the petitioner's apparent lack of a real stake in the controversy:

> Because the court of appeals believed that the DNA profiling evidence in this case was admissible under *Frye* as well as under *Williams* [its decision rejecting *Frye*], this is not an appropriate case in which to resolve the issue [on] which the courts of appeals are in conflict.

Opp. at 12. The Solicitor General, however, did suggest a fundamental agreement with the Second Circuit's rejection of the *Frye* rule: "Rule 702 of the Federal Rules of Evidence does not . . . suggest that the standard for admissibility of novel scientific evidence should be more stringent than the standard that applies to other forms of expert testimony." Opp. at 14.

Assuming that the *Jakobetz* petition is indeed less than ideal for this Court's consideration of the status of *Frye*, the circuit conflict highlighted by the Solicitor General can be decided by the instant petition which presents squarely the holding of the Ninth Circuit -- in premeditated conflict with the Third Circuit, now joined by the Second Circuit -- that the *Frye* test is a permissible rule for excluding evidence.

Prompt resolution of this circuit conflict is essential to vindicating one of Congress's most fundamental policy choices in enacting the Federal Rules of Evidence -- its desire to bring *uniformity* to federal evidence law. The Senate Report accompanying the bill that became the Federal Rules of Evidence cited the need for "a comprehensive code of evidence intended to govern the admissibility of proof in all trials before the Federal courts because of the lack of uniformity and clarity in the present law of evidence on the Federal level." S. Rep. No 93-1277, 93rd Cong., 2d Sess. (1974), at [1974] U.S. Code Cong. & Ad. News 7054. Persistence of the current conflict can only encourage the type of forum-shopping that prevailed under the pre-1975 system in which judges in each jurisdiction crafted and applied their own common-law rules of evidence. Absent a resolution of this conflict parties will increasingly recognize that the rules of evidence now determine the ultimate outcome of their cases, particularly in so-called "mass tort" cases, and claims will be decided not on their merits but rather on the ability of lawyers to maneuver them into courts with friendly rules for scientific evidence. This trend will neither ease existing burdens on federal courts nor encourage efficient and fair resolution of cases.

This conflict has a profound impact on the ultimate outcomes of civil and criminal cases in federal courts nationwide, and this conflict will *not* go away. When this Court, over the dissents of two Justices, declined in 1986 to review the status of *Frye*, *see United States v. Mustafa*, 22 M.J. 165 (C.M.A.), *cert. denied*, 479 U.S. 953 (1986), there might have been good reason to expect that the Third Circuit's comprehensive and powerful *Downing* opinion -- announced in 1985 (*see* note 4, *supra*) -- would win acceptance in other circuits and avoid any need for this Court's review. But inter-circuit disputes have only sharpened, and grounds for reconciliation have disappeared. The tenor of the current conflict is illustrated by the *en banc* Fifth Circuit's much-noted reinvigoration of the *Frye* test in *Christophersen*,[5] and by the Ninth Circuit's equally vigorous embrace of *Frye* in the instant case, followed quickly by the Second Circuit's complete rejection of *Frye* in the *Jakobetz* case. Waiting another Term or longer would not further ventilate the issues and would only guarantee additional frustration of Congress's core goal of ensuring uniform rules of evidence in the federal courts.

2. This Court Should Decide Whether the Lower Federal Courts Possess Inherent Judicial Power to Create Their Own Rules for Excluding Evidence

The Ninth Circuit's decision below stretches the concept of "inherent judicial power" well beyond the breaking point,

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[5] *See, e.g.*, Recent Case, 105 Harv. L. Rev. 791, 795 (1992) (observing that "the real import of [*Christophersen*] is that it breathes new life into the *Frye* rule and counters 'the movement away from the general acceptance test'") (citation omitted); Note, *"Helpful" or "Reasonably Reliable"?: Analyzing the Expert Witness's Methodology Under the Federal Rules of Evidence 702 and 703*, 77 Cornell L. Rev. 350, 382 & n.215 (1992) (noting that "the per curiam opinion [in *Christophersen*] relies on an innovative application of the much-maligned *Frye* test," and that "[a]pplication of *Frye* to a run-of-the-mill civil case is unquestionably a new concept"); *Fifth Circuit Formulates Stiff Test For Admitting Toxic Tort Expert Opinion*, 60 U.S.L.W. 1042 (Sept. 17, 1991); Taylor, *Expert Witness Opinion Eyes; Circuits Split on the Issue*, National Law Journal, Oct. 21, 1991, at 3.

trampling over Congress's express displacement of that power in Fed. R. Evid. 402. In so doing, the decision bypasses the procedural safeguards for evidence rulemaking set forth by Congress in 28 U.S.C. §§ 2071-2077, and it effects substantive revision of rights granted petitioners under state tort law in violation of this Court's *Erie* jurisprudence which must in this context supersede whatever inherent judicial power could otherwise be exercised.

The instant case therefore presents this Court with an opportunity to speak with a united voice concerning the limits of inherent judicial power, a subject which engendered a 5-to-4 split in the recent case of *Chambers v. NASCO, Inc.*, 111 S. Ct. 2123 (1991). The majority in *Chambers* ruled that the scheme of statutes and rules provided by Congress to target bad-faith conduct had not "displace[d] the inherent power to impose sanctions" for such activity. *Id.* at 2134. Although on the facts of the case the majority did not perceive "that the District Court's reliance on the inherent power thwarted the purposes of the other sanctioning mechanisms," *id.* at 2136, the majority reaffirmed that "[b]ecause of their very potency, inherent powers must be exercised with restraint and discretion," *id.* at 2132, and that "the exercise of the inherent power of lower federal courts can be limited by statute and rule, for '[t]hese courts were created by act of Congress.'" *Id.* at 2134 (citation omitted). The majority also reaffirmed that any exercise of inherent powers must not violate the twin aims of this Court's *Erie* jurisprudence, of discouraging forum-shopping and avoiding inequitable administration of the laws. *Id.* at 2137.

Justice Kennedy, in dissent, also emphasized that "[i]nherent powers are the exception, not the rule, and their assertion requires special justification in each case," and that the lower federal courts must not be permitted "to ignore express Rules and statutes on point." *Id.* at 2143 (Kennedy, J., joined by Rehnquist, C.J. and Souter, J., dissenting). Strongly focusing on the *Erie* point, Justice Kennedy expressed concern that permitting use of inherent powers to impose sanctions for prelitigation primary conduct "violates the fundamental tenet of federalism announced in *Erie* by regulating primary behavior that the Constitution leaves to the exclusive province of States," with the

result that "[r]espondent's decision to bring this suit in federal rather than state court resulted in a significant expansion of the substantive scope of his remedy," a "result prohibited by *Erie* and the principles that flow from it." *Id.* at 2148-49. Justice Scalia also voiced serious concerns, arguing among other things that "Congress may prescribe the means by which the courts may protect the integrity of their proceedings," and that "[a] court must use the prescribed means unless for some reason they are inadequate." *Id.* at 2140-41 (Scalia, J., dissenting).

The Ninth Circuit has refused to recognize that its power to impose the *Frye* test has been displaced by enactment of the Federal Rules of Evidence and related procedural rulemaking requirements laid down by Congress. That refusal and the Ninth Circuit's imposition of the *Frye* test to significantly reduce the substantive scope of petitioners' tort remedies under California law in a diversity case reveal a fundamental lack of respect for the limits on inherent judicial power. Such disrespect provides common ground for the majority and dissenting Justices in *Chambers* and presents an important opportunity for this Court to underscore to the lower federal courts basic axioms regarding the limits of judicial power.

The power of the federal courts -- including even *this* Court -- "to prescribe rules of procedure and evidence for the federal courts exists only in the absence of a relevant Act of Congress." *Palermo v. United States*, 360 U.S. 343, 353 n.11 (1959). Congress possesses the authority under the Necessary and Proper Clause "to enact laws carrying into execution the powers vested in other departments of the Federal Government," *Kaiser Aetna v. United States*, 444 U.S. 164, 172 n.7 (1979), including an "undoubted power to regulate the practice and procedure of federal courts." *Sibbach v. Wilson & Co.*, 312 U.S. 1, 9 (1941).

Unlike the loosely constructed corpus of sanctions law considered in *Chambers*, the law of evidence has been comprehensively and rigorously addressed by Congress, and Congress has spoken specifically to the issue of which grounds justify the exclusion of relevant evidence. By failing to list judge-made rules of exclusion, Congress has displaced the sort of inherent judicial authority which the Ninth Circuit below purports to exercise. In Fed. R. Evid. 402 Congress decreed:

> All relevant evidence is admissible, except as otherwise provided [1] by the Constitution of the United States, [2] by Act of Congress, [3] by these rules or [4] by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

(Brackets added).

This list does not contain the *Frye* test or any other customized admissibility limits applied by the lower federal courts prior to enactment of the Rules, and by some circuits notwithstanding Congress's direction still today. Indeed, the *only* judge-made rules that Congress decided to permit under Rule 402 are rules promulgated by *this Court* "pursuant to statutory authority" -- that is, its authority to enact rules conferred by 28 U.S.C. § 2071(a), subject to all the elaborate procedural requirements of 28 U.S.C. §§ 2071-2977. *See* page 2, *supra*. Congress pointedly refused to authorize the courts of appeals or the district courts to make their own supplementary evidence rules even after notice-and-comment rulemaking pursuant to 28 U.S.C. § 2071. Any inference that Congress nevertheless left the lower federal courts free to do the same thing through *decisional law* that bypasses all these procedural constraints is ruled out by the wording of Fed. R. Evid. 501. With Rule 501, Congress created an exception to the general ban on decisional rules of exclusion by permitting development of a federal law of privileges under "the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience." Congress knew the precise words to use when it wished to authorize new decisional rules of evidence exclusion, and Congress failed to use such words in the area of expert testimony, governed by Rules 701 to 706 of the Federal Rules of Evidence.

Apart from the exact and exacting language chosen, the function of Rule 402 is obvious: it carries out Congress's central goal of bringing uniformity and coherence to federal evidence law. Rule 402 is "'the keystone to the whole scheme,'" designed both "to sweep away all pre-existing rules of exclusion" and "to modify this sweeping repeal by stating the relationship between the repealer and the pre-existing law as well as making clear that the rest of the Evidence Rules are exceptions to the basic rule of

relevance." 22 Charles Alan Wright & Kenneth W. Graham, Jr., *Federal Practice and Procedure: Evidence* § 5192, at 177 (1978).

Analysis of the purpose animating Rule 402, of course, is hardly necessary. Even if the *Frye* rule had been universally embraced and applied by all circuits prior to the enactment of the Federal Rules of Evidence it could not have survived given the language of those Rules. To have displaced *Frye* Congress need not have "really meant" to do so. Such is the clear teaching of Chief Justice Rehnquist's opinion for the Court in *Bourjaily v. United States*, 483 U.S. 173 (1987), which considered the status of the long-established common-law "bootstrapping rule" under the co-conspirator exception to the hearsay rule. The common-law bootstrapping rule had always barred hearsay statements *themselves* from being used to prove conspiracy and to thereby trigger the co-conspirator exception to the prohibition on hearsay, because without the bootstrapping rule, "'hearsay would lift itself up by its own bootstraps to the level of competent evidence.'" *Id.* at 177 (citation omitted). Addressing whether the bootstrapping rule had survived enactment of the Federal Rules of Evidence, Chief Justice Rehnquist noted Rule 104(a)'s provision that when deciding the admissibility of evidence, a trial court "is not bound by the rules of evidence except those with respect to privileges," and he observed: "That would seem to many to be the end of the matter. Congress has decided that courts may consider hearsay in making these factual determinations." *Id.* at 177-78.

Chief Justice Rehnquist then stated:

> But petitioner nevertheless argues that the bootstrapping rule, as most Courts of Appeals have construed it, survived this apparently unequivocal change in the law unscathed and that Rule 104, as applied to the admission of co-conspirator's statements, does not mean what it says. We disagree.
>
> Petitioner claims that Congress evidenced no desire to disturb the bootstrapping rule, which was embedded in the previous approach, and we should not find that Congress altered the rule without affirmative evidence so indicating. It would be extraordinary to require legislative history to *confirm* the plain meaning of Rule 104.

Id. at 178 (emphasis in original).

Bourjaily is hardly an isolated exception. This Court has consistently taken the approach that the Federal Rules of Evidence are to be interpreted just like any other statute, with no judicial license for extra creativity. *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163 (1988) ("[b]ecause the Federal Rules of Evidence are a legislative enactment, we turn to the 'traditional tools of statutory construction,' in order to construe their provisions") (citation omitted). *See generally* Jonakait, *The Supreme Court, Plain Meaning, and the Changed Rules of Evidence*, 68 Tex. L. Rev. 745 (1990). Yet this message has been largely lost on the lower courts, including the Ninth Circuit below; only a handful of circuit court opinions have cited the *Rainey* decision or noted that the Federal Rules of Evidence are a statute. One of the few lower federal court opinions to heed this vital admonition is *United States v. Rogers*, 918 F.2d 207, 209 (D.C. Cir. 1990) (Thomas, J.) (recognizing that on evidence questions a court must "begin as . . . with any statute, with the language of the rules themselves").

Despite the instruction of both Congress and this Court, the court below has chosen to advance its own concerns about appropriate evidence policy by brazenly enacting what must be viewed as a judicial amendment to the Federal Rules of Evidence in the Ninth Circuit. The Ninth Circuit's attempt to function as "a sort of junior-varsity Congress," *Mistretta v. United States*, 488 U.S. 361, 427 (1988) (Scalia, J., dissenting), should be overturned.

A total of six circuits persist in applying the judge-made *Frye* rule despite congressional displacement of the rule. *See* note 3, *supra*. But two of these courts -- including the Ninth Circuit below -- have further exceeded their judicial authority by using the accident of their diversity jurisdiction to impose on the citizens of the various States within their circuits a federal rule of decision that strikes at the heart of this Court's doctrine under *Erie Railroad v. Tompkins*, 304 U.S. 64 (1938).

Until recently, use of the *Frye* rule in federal court was almost entirely limited to criminal trials of federal statutory crimes. *Frye* itself was a criminal case, in which the D.C. Circuit refused to admit evidence obtained from a predecessor of

the modern polygraph, on the basis that authorities in the field had not yet accepted the polygraph machine technique as valid, and thus that "'inexperienced persons are unlikely to prove capable of forming a correct judgment upon it.'" 293 F. at 1014 (quoting defense brief). The court's test of admissibility was *ad hoc* (as the court could find no cases bearing on admissibility) and notoriously vague, reading in full:

> Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.

Ibid.

The D.C. Circuit later explained that "the *Frye* test protects prosecution and defense alike by assuring that a minimal reserve of experts exists who can critically examine the validity of a scientific determination in a particular case." *United States v. Addison*, 498 F.2d 741, 743 (D.C. Cir. 1974). For many years, tied to this original criminal law context, the *Frye* test was employed to bar from federal criminal trials a host of scientific evidence involving new and complicated technologies, primarily to protect criminal defendants from evidence that might be overvalued by the jury.[6] Prior to its radical alteration of its *Frye* test in the decision below, the Ninth Circuit itself recognized this core feature of *Frye*. *See United States v. Fleishman*, 684 F.2d 1329, 1337 (9th Cir.), *cert. denied*, 459 U.S. 1044 (1982) (stating that special rules like the *Frye* test were created in criminal cases out of a "concern[] with the possible prejudice to

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[6] Examples include the forward-looking infrared imaging system, *see United States v. Kilgus*, 571 F.2d 508, 510 (9th Cir. 1978); "voiceprints," *see Addison, supra*, 498 F.2d at 743; neutron activation analysis, *see United States v. Stifel*, 433 F.2d 431, 436 (6th Cir. 1970), *cert. denied*, 401 U.S. 994 (1971); and sodium pentothal ("truth serum"), *see Lindsey v. United States*, 237 F.2d 893, 896 (9th Cir. 1956).

the defendant's right to a fair trial of admitting testimony of purported experts based upon insufficiently substantiated scientific theories, techniques or tests"). Before the enactment of the Federal Rules of Evidence, and given the acknowledged responsibility of the lower federal courts to ensure the orderly and fair conduct of criminal proceedings, there was perhaps little basis for questioning the institutional legitimacy of the *Frye* rule and no basis for scrutiny under *Erie*.

The recent decision of the *en banc* Fifth Circuit in *Christophersen* and of the Ninth Circuit in the decision below has pioneered a vastly expanded version of the *Frye* test in civil diversity litigation that acts as a means of cutting short the opportunity for civil trials based on a perception that particular expert *reasoning* is "too novel." So utilized, the *Frye* rule represents a shocking violation of "[t]he *Erie* rule [which] remains a vital expression of the federal system and the concomitant integrity of the separate States." *Ferens v. John Deere Co.*, 110 S. Ct. 1274, 1280 (1990) (per Kennedy, J.).

The *Christophersen* decision rested on an innovative and expansive application of *Frye* to an unremarkable state tort case. *See* note 5, *supra*. Sketching the judicial activism at play, Chief Judge Clark stressed that "[u]ntil today, this circuit has limited *Frye* to a narrow class of federal criminal cases to which *Erie* does not apply." 939 F.2d at 1120 (Clark, J., concurring in the result). Furthermore, the four dissenters (with the agreement of Chief Judge Clark) noted that the *en banc* majority had extended the matters to which *Frye* was applied beyond bare consideration of "novel device[s] or technique[s]" to "subject[] expert reasoning to judge-determined reliability." 939 F.2d at 1132 (Reavley, J., dissenting). In other words, an expert reasoning from routine sources of information would be scrutinized to determine whether his final *conclusions* are "acceptable," that is, consistent with the views of many or most other scientists. As Judge Reavley explained the *Erie* problems posed by this transformation:

> Until today, we soundly limited the *Frye* doctrine to particular techniques, "novel scientific evidence," that reflect the factual context of *Frye*. To my knowledge, the Fifth Circuit has never excluded otherwise relevant evidence strictly on the basis of lack of general scientific acceptance.

> To do so would impose a significantly heavier burden of proof and persuasion on the offering party.

Id. at 1133 (citations omitted).

Such a regime of special presumptions -- barring a finding of causation until a judicially determined quantum of proof can be mustered by a party through experts whose conclusions are drawn from standard sources which enjoy "general scientific acceptance" -- clearly effects "substantive" constraints within the meaning of the *Erie* doctrine. *See, e.g., Dick v. New York Life Ins. Co.*, 359 U.S. 437, 446-47 (1959); *Cities Service Oil Co. v. Dunlap*, 308 U.S. 208 (1939). As the *Christophersen* dissenters concluded, such rules are so decisive in nature that their imposition "substantially affect[s] the rights of claimants and the proof required for their compensation." 939 F.2d at 1135 (Reavley, J., dissenting). As the dissenters pointed out, "[u]nder Texas law, claimants [did] not suffer these disadvantages," and thus there was "no doubt that in Texas courts Mrs. Christophersen would have received her jury trial." *Id.* at 1135-36 & n.48. "This lack of congruence with the state courts in cases dependent on our diversity jurisdiction," the dissenters argued, "is fundamentally at odds with the Supreme Court's decision in *Erie*. As a result, we encourage reverse forum shopping and deprive plaintiffs of the substantive rights that should be available to them under state law." *Id.* at 1137-38 (King, J., dissenting). The decision of the Ninth Circuit below suffers from precisely the same defect under *Erie*.

In elaborating on their own variant of the *Frye* test "for determining the underlying reliability of a new scientific technique," first announced in the criminal case of *People v. Kelly*, 549 P.2d 1240, 1244 (Cal. 1976), California courts have consistently rejected use of the *Frye* test in the manner dictated by the Ninth Circuit decision below. The leading case is *People v. McDonald*, 690 P.2d 709, 723-24 (Cal. 1984), in which the California Supreme Court overruled a trial court's refusal to permit a psychologist to testify concerning data on the asserted unreliability of eyewitness testimony. Focusing on the trial court's ruling that such testimony "is not yet 'scientific enough' to be admissible," the California Supreme Court stated:

It is important to distinguish in this regard between *expert testimony* and *scientific evidence*. When a witness gives his personal opinion on the stand -- even if he qualifies as an expert -- the jurors may temper their acceptance of his testimony with a healthy skepticism born of their knowledge that all human beings are fallible. But the opposite may be true when the evidence is produced by a machine: like many laypersons, jurors tend to ascribe an inordinately high degree of certainty to proof derived from an apparently "scientific" mechanism, instrument or procedure. . . . "[T]he rule serves its salutary purpose of preventing the jury from being misled by unproven and ultimately unsound scientific methods."

Here, by contrast, no such methods are in issue. We have *never* applied the *Kelly-Frye* rule to expert medical testimony, even when the witness is a psychiatrist and the subject matter is as esoteric as the reconstitution of a past state of mind or the prediction of future dangerousness, or even the diagnosis of an unusual form of mental illness not listed in the diagnostic manual of the American Psychiatric Association . . . .

Id. at 724 (emphasis added) (citations omitted). Subsequent decisions have ruled that expert medical testimony on the cause of an injury cannot be subjected to the *Frye* rule, even where such testimony is novel and unsupported by published scientific studies.[7]

The *Frye* test imposed by the Ninth Circuit on the citizens of California directly flouts *McDonald* and subsequent decisions by

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[7] *See also People v. Pitts*, 223 Cal.App.3d 606, 865 (1990) ("there is a difference between development of a new scientific technique -- a novel method of proof -- and development of a body of medical knowledge and expertise. . . . The expression of an expert medical opinion as to the cause of a wound or injury falls outside of the realm of what is subject to the *Kelly-Frye* rule") (citation omitted); *McCleery v. City of Bakersfield*, 170 Cal.App.3d 1059, 1071 (1985) (applying *McDonald* rule to admit scientific opinions even though "the proffered testimony in the instant case was novel -- the trial court characterized appellants' efforts as 'trying to plow new ground in this case' -- and was not backed by extensive scientific literature and scholarly studies as was the proffered testimony in *McDonald*").

imposing *Frye*'s "general acceptance" requirement to preclude from jury consideration the conclusions put forth in the testimony of qualified medical experts as to the cause of petitioners' limb defects. Even though the "reanalysis of epidemiological studies" relied on in part by some of petitioners' experts "is generally accepted by the scientific community," (A4), the Ninth Circuit excluded all the opinions from evidence and ended the entire case because the opinions had not been "subject to verification and scrutiny by others in the field" through the peer-review publication process. The Ninth Circuit mandated that the opinions "meet *all* of the essential requirements . . . [to] satisfy [the Ninth Circuit's] rigorous standard." (A4-A5.) This "rigorous standard" is in flat violation of *Erie* and the Rules of Decision Act, which together "mandate[] that a federal court sitting in diversity apply the substantive law of the forum State, absent a federal statutory or constitutional directive to the contrary." *Salve Regina College v. Russell*, 111 S. Ct. 1217, 1218 (1991) (citing *Erie*, 304 U.S. at 78; 28 U.S.C. § 1652 (Rules of Decision Act)). Because the decision below permits Merrell to disable future California Bendectin cases merely by removing them to federal court it violates *Erie*'s "twin aims" of discouraging forum-shopping and avoiding inequitable administration of the laws. *See Chambers*, *supra*, 111 S. Ct. 2123, 2137 (1991) (majority opinion). *See also id.* at 2148-49 (Kennedy, J., dissenting); *Stewart Organization, Inc. v. Ricoh Corp.*, 108 S. Ct. 2239, 2248-50 (1988) (Scalia, J., dissenting). These fundamental issues merit this Court's plenary attention.

3. This Court Should Decide Whether the Lower Federal Courts May Delegate Control Over Admissibility of Scientific Expert Opinion Testimony to the Editors of Peer-Reviewed Journals

The final issue warranting review is the Ninth Circuit's use of the *Frye* rule to delegate control over admissibility of scientific expert opinion testimony to the editors of peer-reviewed journals. *See* pp. 7-9, *supra*. Under the decision below, if an expert witness wishes to rely upon his own analysis of data in a published scientific study, but after full study reaches a conclu-

sion opposite that of the author of the study, he may offer his opinion *only* if that opinion "is subjected to verification and scrutiny by others in the field" (A4) through the peer-review process *and* can convince the editors of a peer-review journal to publish the analysis. (A5.) The court below regarded this as a wise requirement, on the basis that the peer review process "is one of the hallmarks of reliable scientific investigation" -- that "'the science of publication, replication, and verification, the science of consensus and peer review'" is "'good science'" and "'the best test of certainty we have.'" (A5 & n.3 (citation omitted).) This requirement mandates that such opinions may be presented to a jury only if "accepted by recognized authorities in the field" (A3), in accord with the central aim of the *Frye* rule of "assur[ing] that those most qualified to assess the general validity of a scientific method will have the determinative voice." *United States v. Addison*, 498 F.2d 741, 744 (D.C. Cir. 1974).

The Ninth Circuit's requirement that opinions be published in peer-reviewed journals before they can be presented at trial, and the concomitant delegation of substantial authority over evidence in federal trials to the private editors of these journals, is a blatant abuse of judicial power. There is absolutely no language in any relevant statute or rule authorizing such a requirement. To be sure, whether or not an expert's conclusions are peer-reviewed and published may well affect the credibility of his testimony. The Ninth Circuit urged an "added dose of skepticism" especially where studies are performed in anticipation of litigation. (A5 n.3.) But our system of justice entrusts such practical grounds for skepticism of a witness's testimony to the jury -- not to judges, and not to private journalists anointed by judges -- and the Seventh Amendment bars the strange rule imposed by the court below.[8]

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[8] "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of the judge," *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986), and by displacing these jury functions the decision below violates the Seventh Amendment. The Ninth Circuit's delegation of credibility assessments to the editors of peer-reviewed journals obviously has no conceivable analogue in procedural law circa 1791 and therefore cannot survive constitutional scrutiny. *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 336-37 (1979). The Seventh Amendment's history makes clear that its central mission is to check the power of autocratic, life-tenured federal judges by entrusting factual disputes to empaneled jurors who are independent of the sovereign's judges, however inefficient this can be at times. *See id.* at 337-56 (Rehnquist, J., dissenting); *see also Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 83 (1989) (White, J., dissenting) ("'The function of the civil jury is to diffuse the otherwise autocratic power and authority of the judge'").

As the Ninth Circuit below acknowledged (A4 n.2), its decision is in conflict with the Third Circuit's decision in *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990), a conflict that independently merits this Court's review.[9]

Lacking in any legal support, the rule imposed below is equally lacking in scientific support. The Ninth Circuit is profoundly mistaken in regarding the peer-reviewed publication process as built on a "search for truth," so that it may logically serve the truth-seeking function of the trial process. As a former editor of the *Journal of the American Medical Association* has remarked, "[p]eer review is far from being a 'perfect sausage machine for grinding out the truth.' . . . 'Just because peer review is about a review of scientific data doesn't mean that it is itself a scientific process. . . . We need more realistic, human expectations.'" L.A. Times, May 22, 1989, Pt. II, at 3 col. 1 (quoting Elizabeth Knoll). The editor-in-chief of *The New England Journal of Medicine* agrees that "the peer review process is 'not meant to determine ultimate truth or falsity.' [I]ts main functions [are] 'to improve the quality of what is published' and 'to help editors decide what they want to publish in their journals . . . .'" *Ibid.* (quoting Dr. Arnold S. Relman). As numerous commentators have documented, neither the objectives of peer review nor its procedures are suited to the determination

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[9] On the issue of whether a court may insist that an expert go through peer-review and publication before presenting his opinion, *DeLuca* rejected the theory that "an expert [must] accept the conclusions reached by the authors of studies if the expert wishes to utilize the data underlying those studies as a basis for testimony." 911 F.2d at 954. It held, further, that: "[T]he Federal Rules of Evidence contain no requirement that an expert's testimony be based upon reasoning subjected to peer-review and published in the professional literature." *Ibid.*

of truth.[10] The Ninth Circuit's bizarre "publish-or-perish" edict for expert testimony is bad law and bad science, has no place in federal jurisprudence, and merits prompt review.

CONCLUSION

For all these reasons, certiorari should be granted.

Respectfully submitted,

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July 7, 1992

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[10] *See, e.g.*, Charles W. McCutchen, *Peer Review: Treacherous Servant, Disastrous Master*, Technology Review, Oct. 1991, at 28 ("Science uses peer review to determine which projects to pay for and which articles to publish, and, recently, to judge cases of alleged misconduct"), 30 ("Peer review resists investigation. Only insiders know the details of each decision. They may not tell the truth"), 33 ("Unfortunately, the power of referees, usually anonymous, permits self-interest, jealousy, revenge, and other unworthy motives to influence decisions"); Jonathan Schlefer, *Truth, Beauty, and Peer Review*, Technology Review, Oct. 1990, at 5 ("Our society often wants to see peer review as a mechanical certification of truth for which no one has to take responsibility. No such mechanism is conceivable"); Lawrence K. Altman, M.D., *The Doctor's World: Peer Review is Challenged*, N.Y. Times, Feb. 25, 1986, at C3 col. 1 ("[R]eferees are often selected as part of 'an old-boy network' rather than randomly as a scientific process might do. Since many journals are run on shoestring budgets, the possibilities of conflicts of interest in the peer review process seem apparent. One potential conflict that has received too little attention is between medical journal editors and the drug companies whose advertising they depend on for income"); Lawrence K. Altman, *Study Says Drug Ads in Medical Journals Frequently Mislead*, N.Y. Times, June 1, 1992, at A1, col. 1 ("In 1991, drug companies spent $351 million on advertisements in medical journals").

The combined effect of all these influences is reflected in a recent *New York Times* article which spotlighted a five-year delay in publication of a dissenting "re-analysis" of the efficacy of a frequently prescribed drug, resulting from "academia s surprising aversion to dissent," "the strong ties between scientific journals, academia and the drug industry," and "professional jealousies." *See Hidden Discord Over Right Therapy*, N.Y. Times, Dec. 24, 1991, at B6 col. 1.

APPENDICES

APPENDIX A

Decision of the United States Court of Appeals for the Ninth Circuit, affirming the district court's grant of summary judgment for respondent, dated December 20, 1991 ..... A1

APPENDIX B

Memorandum Decision and Order of the United States District Court for the Southern District of California, granting summary judgment for respondent, dated November 1, 1989 ..... A6

APPENDIX C

Order of the Ninth Circuit, denying rehearing, dated April 8, 1992 ..... A18

APPENDIX A

UNITED STATES COURT OF APPEALS
For the Ninth Circuit

No. 90-55397

WILLIAM DAUBERT; JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT, a minor; ANITA DE YOUNG, individually, and As Guardian Ad Litem for ERIC SCHULLER,

Plaintiffs-Appellants,

v.

MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation,

Defendant-Appellee.

Appeal from the United States District Court
For the Southern District of California

(December 20, 1991)

Before: Alex Kozinski and Diarmuid F. O'Scannlain, Circuit Judges, and Stephen M. McNamee,* District Judge.

KOZINSKI, Circuit Judge:

Plaintiffs Jason Daubert and Eric Schuller suffer from limb reduction birth defects. They allege that these defects resulted

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* The Honorable Stephen M. McNamee, United States District Judge for the District of Arizona, sitting by designation.

from the fact that their mothers used Bendectin, a prescription anti-nausea drug, during pregnancy. The plaintiffs seek damages from the drug's manufacturer, defendant Merrell Dow Pharmaceuticals.

Plaintiffs' evidence of causation consisted primarily of expert opinion based on *in vitro* and *in vivo* animal tests, chemical structure analyses and the reanalysis of epidemiological studies. Among the contrary evidence proffered by Merrell Dow was the affidavit of a physician and epidemiologist who reviewed all of the available literature on the subject, which included more than 30 published studies involving over 130,000 patients, and concluded that no published epidemiological study had demonstrated a statistically significant association between Bendectin and birth defects. Plaintiffs do not challenge this summary of the published record.

The district court determined that plaintiffs could not meet their burden of proving that Bendectin caused Jason's and Eric's birth defects and granted Merrell Dow's motion for summary judgment. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 727 F. Supp. 570 (S.D. Cal. 1989).

A. Expert opinion based on a scientific technique "is admissible if it is generally accepted as a reliable technique among the scientific community." *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985) (citing *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923)). We impose this requirement because such evidence "creates a substantial danger of undue prejudice or of confusing the issues or of misleading the jury . . . because of its aura of special reliability and trustworthiness." *United States v. Amarel*, 488 F.2d 1148, 1152 (9th Cir. 1973); *see also* Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 HARV.L.REV. 40, 50-52 (1901). Moreover, whether expert opinion can satisfy this requirement is reviewed *de novo* by an appellate court, for "the answer to the question about the reliability of a scientific technique or process does not vary according to the circumstances of each case. It is therefore inappropriate to view this

threshold question of reliability as a matter within each trial judge's individual discretion." *Reed v. State*, 391 A.2d 364, 367 (Md. 1978); *see also United States v. Williams*, 583 F.2d 1194, 1197-1201 (2d Cir. 1978) (applying *de novo* review to the question of the general acceptance of a scientific technique), *cert. denied*, 439 U.S. 1117 (1979).

For expert opinion based on a given scientific methodology to be admissible, the methodology cannot diverge significantly from the procedures accepted by recognized authorities in the field. If it does so diverge, it cannot be shown to be "generally accepted as a reliable technique," *Solomon*, 753 F.2d at 1526, and a district court must exclude it. If such evidence is admitted and materially affects the verdict, a judgment supported by this evidence cannot stand. *See Lindsey v. United States*, 237 F.2d 893, 897-98 (9th Cir. 1956).

B. Whether Bendectin is responsible for limb reduction defects is not a new question in the federal courts. Four of our sister circuits have considered whether plaintiffs could establish such responsibility in the absence of critically analyzed epidemiological studies establishing a connection between the use of the drug and the birth defects. *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989); *Lynch v. Merrell-National Labs.*, 830 F.2d 1190 (1st Cir. 1987) (opinion by Noonan, J., sitting by designation). Three circuits have concluded that the plaintiffs could not establish such a link. Considering largely the same evidence presented to the district court below, these courts held that the animal and chemical studies were insufficient to establish a link between Bendectin and birth defects, *Brock*, 874 F.2d at 313-15; *Richardson*, 857 F.2d at 830; *Lynch*, 830 F.2d at 1194, in part because the plaintiffs' own experts acknowledged the need to verify such data with epidemiological evidence.

Brock, 874 F.2d at 314; *Richardson*, 857 F.2d at 830.[1] These courts were unwilling to allow plaintiffs to rely on reanalyses of epidemiological studies because these reanalyses had neither been published nor subjected to the rigors of peer review. They found the methodology particularly problematic in light of the massive weight of the original published studies supporting the defendant's position, all of which had undergone full scrutiny from the scientific community. *See Brock*, 874 F.2d at 312-13; *Richardson*, 857 F.2d at 831; *Lynch*, 830 F.2d at 1193-96; *see also Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1111 n.8 (5th Cir. 1991) (en banc).[2]

Plaintiffs argue that reanalysis is a generally accepted scientific technique, so it follows that their experts were basing their opinions on a permissible methodology. But the reanalysis of epidemiological studies is generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field. *See* Dore, *A Commentary on the Use of Epidemiological Evidence in Demonstrating Cause-in-Fact*, 7 HARV.ENV'L L.REV. 429, 438-39 (1983) (discussing requirements for original epidemiological studies). Plaintiffs' reanalyses do not comply with this standard; they were unpublished, not subjected to the normal peer review process, and generated solely for use in litigation.[3] It does not suffice that the expert's methodology meet *some* of the requirements imposed by the scientific community; it must meet *all* of the essential requirements. Selective borrowing from generally accepted scientific methodology does not satisfy *Solomon*'s rigorous standard.

[1] *Richardson* and *Lynch* held that expert testimony that Bendectin caused birth defects, based solely on animal and chemical tests and reanalyses of epidemiological studies, was inadmissible under Federal Rule of Evidence 703, and that therefore plaintiffs had failed to present evidence to support a jury verdict in their favor. 857 F.2d at 830-831; 830 F.2d at 1193-96. *Brock* did not hold that the plaintiffs' expert testimony was inadmissible, but did decide that it was insufficient to support the jury's verdict. 874 F.2d at 315.

[2] The Third Circuit has left open the possibility that expert testimony based on the reanalysis of epidemiological studies may be admissible if it can be shown to be reliable and not too likely to overwhelm, confuse or mislead the jury. *See DeLuca*, 911 F.2d at 955 (remanding case for district court to reconsider the admissibility of plaintiffs' expert testimony). Because the Third Circuit has specifically rejected the *Frye/Solomon* "generally accepted" standard, *United States v. Downing*, 753 F.2d 1224, 1236-37 (3d Cir. 1985), we find the court's analysis in *DeLuca* to be contrary to our established precedent and decline to follow it.

C. *Lynch*, *Richardson* and *Brock* reflect a well-founded skepticism of the scientific value of the reanalysis methodology employed by plaintiffs' experts; they recognize that "the best test of certainty we have is good science -- the science of publication, replication, and verification, the science of consensus and peer review." P. Huber, *Galileo's Revenge: Junk Science in the Courthouse*, 228 (1991). For the convincing reasons articulated by our sister circuits, we agree with the district court that the available animal and chemical studies, together with plaintiffs' expert reanalysis of epidemiological studies, provide insufficient foundation to allow admission of expert testimony to the effect that Bendectin caused plaintiffs' injuries. Accordingly, plaintiffs could not satisfy their burden of proving causation at trial. *See Christophersen*, 939 F.2d at 1109 ("When the contested evidence is essential to the cause of action and the trial court has excluded the evidence, we may decide the appeal . . . solely on the basis of the soundness of the evidentiary ruling. For if we uphold the exclusion of essential evidence, the [review of the summary judgment ruling] becomes academic.").

AFFIRMED.

[3] Scientific studies conducted in anticipation of litigation must be scrutinized much more carefully than studies conducted in the normal course of scientific inquiry. This added dose of skepticism is warranted, in part, because studies generated especially for use in litigation are less likely to have been exposed to the normal peer review process, which is one of the hallmarks of reliable scientific investigation. *See Brock*, 874 F.2d at 313; *Richardson*, 857 F.2d at 831 n.55; *Perry v. United States*, 755 F.2d 888, 892 (11th Cir. 1985).

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT
OF CALIFORNIA

WILLIAM DAUBERT, et al., *Plaintiffs*,	)	
v.	)	
MERRELL DOW PHARMACEUTICALS, INC., et al., *Defendants*.	)	CIVIL NOS. 84-2013-G(IEG), 84-2929-G(IEG) (Consolidated)
MICHAEL SCHULLER et al., *Plaintiffs*,	)	
v.	)	
MERRELL DOW PHARMACEUTICALS, INC., et al., *Defendants*.	)	

MEMORANDUM DECISION AND ORDER

EARL B. GILLIAM, UNITED STATES DISTRICT JUDGE:

The defendant's motion for summary judgment was scheduled for hearing on October 6, 1989, in Courtroom 7 before the Honorable Earl B. Gilliam. Plaintiffs were represented by Mary Gillick and Barry Nace. George Berry, Robert Dickson and Pamela Yates appeared on behalf of defendant. Having considered the points and authorities and oral argument of counsel, the court issues this memorandum decision and order granting defendant's motion for summary judgment.

FACTS

This case involves personal injuries sustained by plaintiffs. Infant plaintiffs and their guardians ad litem seek damages from defendant for injuries (limb reduction birth defects) allegedly sustained as a result of the mothers' ingestion of Bendectin during pregnancy. Bendectin is a prescription pharmaceutical product previously manufactured by Merrell Dow, indicated solely for the treatment of nausea and vomiting during pregnancy. Defendant has moved for summary judgment, arguing that plaintiffs have failed to sustain their burden of establishing a genuine issue of material fact regarding causation.

DISCUSSION

Summary judgment is proper "after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. . . ." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "[T]h[e] standard [for granting summary judgment] mirrors the standard for a directed verdict under Federal Rule of Civil Procedure 50(a). . . ." *Id.* at 323 (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986)).

In this case the defendant has moved for summary judgment. Plaintiffs, who have the burden of proof by a preponderance of the evidence, oppose the motion. The court must therefore determine "whether a fair-minded jury could return a verdict for the plaintiff [based] on the evidence presented." *Anderson v. Liberty Lobby, Inc.* 477 U.S. at 251-252. The court must view the evidence in a light most favorable to plaintiff, however, "[t]he evidence is insufficient if the strongest inference to be drawn in the plaintiff's favor is that defendant's negligence could *possibly* have been the cause of the accident." *Bieghler v. Kleppe*, 633 F.2d 531, 533 (9th Cir. 1980) (emphasis in original) (citing *Neely v. St. Paul Fire & Marine Insurance Co.*, 584 F.2d 341, 345 (9th Cir. 1978)). The plaintiff must show that defendant's negligence "was more probably than not the proximate cause of the accident" to defeat summary judgment and take the

issue to a jury. *Bieghler* at 533. The court should exclude inadmissible evidence objected to by either party prior to ruling upon the motion. *See, Hollingsworth Solderless Terminal Co., v. Turley* 622 F.2d 1324, 1335 (9th Cir. 1980).

Federal Rule of Evidence (FRE) 703, restricts the admissibility of scientific evidence. "A necessary predicate to the admission of scientific evidence is that the principle upon which it is based 'must be sufficiently established to have general acceptance in the field to which it belongs.'" *United States v. Kilgus*, 571 F.2d 508, 510 (9th Cir. 1978). Therefore, expert opinion not based on facts or data "of a type reasonably relied upon by experts in the particular field" is not helpful, but instead is confusing or misleading and should therefore be excluded. *See*, Fed.R.Evid. 403. *See also Barrel of Fun, Inc. v. State Farm Fire and Casualty Co.*, 739 F.2d 1028, 1033 (5th Cir. 1984) (excluding expert's opinion based on polygraph test). "Whether an expert's opinion has an adequate basis, and whether without it an evidentiary burden has been met, are matters of law for the court to decide." *Richardson v. Richardson-Merrell*, 857 F.2d 823, 829 (D.C.Cir. 1988), *cert. denied*, 107 L.Ed. 2d 171 (1989).

There are two schools of thought governing expert testimony in these Bendectin cases, and one seems to be prevailing in the federal courts. Unfortunately for the plaintiffs, the prevailing school of thought warrants summary judgment in this case.

The prevailing school is best exemplified by *Brock v. Merrell Dow Pharmaceuticals*, 874 F.2d 307 (5th Cir. 1989), *modified*, 884 F.2d 166 (5th Cir. 1989), *rehr'g denied, en banc*, 884 F.2d 167 (5th Cir. 1989) where the court held the following:

> We find, in this case, the Brocks' failure to present statistically significant epidemiological proof that Bendectin causes limb reduction defects to be fatal to their case.

Id. at 313. The court also noted:

> Hopefully, our decision will have the effect of encouraging district judges faced with medical and epidemiological proof

> in subsequent toxic tort cases to be especially vigilant in scrutinizing the basis, reasoning, and statistical significance of studies presented by both sides. However, we do not wish this case to stand as a bar to future Bendectin cases in the event that new and statistically significant studies emerge which would give a jury a firmer basis on which to determine the issue of causation.

Id. at 315. Several other cases are in accord with this reasoning. *See, Richardson v. Richardson-Merrell, supra; Lynch v. Merrell-National Laboratories*, 830 F.2d 1190 (1st Cir. 1987); *Hull v. Merrell Dow Pharmaceuticals, Inc.*, 700 F.Supp. 28 (S.D.Fla. 1988); *In Re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, 624 F.Supp. 1212 (S.D.Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988), *cert. denied* 109 S.Ct. 788 (1989); *Thompson v. Merrell Dow Pharmaceuticals, Inc.*, 229 N.J.Super. 230, 551 A.2d 177 (1988).

In medical cases like this one, courts must "critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to consistently and rationally resolve the disputes before them." *Brock*, 874 F.2d at 310. Absent a scientific understanding of the cause of the birth defects at issue in Bendectin cases, causation may be shown only through reliance upon epidemiological evidence. *See, Richardson v. Richardson-Merrell; Lynch v. Merrell-National Laboratories. See also In Re Agent Orange Product Liability Lit.*, 611 F.Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2nd Cir. 1987) (stating that epidemiological studies were "the only useful studies having any bearing on causation" in Agent Orange cases).

In *Richardson*, Dr. Done, the plaintiff's expert, relied upon 1) chemical structure activity analysis, 2) *in vitro* (test tube) studies, 3) *in vivo* (animal teratology) studies, and 4) reanalysis of epidemiology studies. He used the results of these four types of studies to conclude that within a reasonable degree of certainty, Bendectin causes birth defects. The court concluded that Dr. Done's testimony lacked an adequate scientific basis:

> These three types of studies -- chemical, *in vitro*, and *in vivo* -- cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. Studies of this kind singly or in combination are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence.

Richardson, 857 F.2d at 830. The court also rejected the reanalysis of the epidemiological studies:

> Dr. Done further admitted that no one who had published work on Bendectin had concluded that there was a statistically significant association between Bendectin and limb reduction defects. . . . Only by recalculating the data was Dr. Done able to obtain what he deems a statistically significant result. Moreover, the studies rejected by Dr. Done had been published in peer-reviewed scientific journals, while Dr. Done has neither published his recalculations nor offered them for review.

Id. at 831 (emphasis added).

The plaintiffs rely on *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C.App. 1986) and other cases which basically give more deference to the expert's opinion. *Oxendine* is the leading Bendectin case in this regard, and the appellate court found that Dr. Done had a sufficient foundation for his testimony when he relied upon chemical analyses, animal studies, *in vitro* studies and recalculations of epidemiological studies:

> Dr. Alan Done, appellant's sole causation witness, had testified that no conclusion about Bendectin's effect on humans could be drawn from any of the four types of scientific data upon which he principally relied when each type was considered separately from the others. The [trial] court focused on this fact and concluded that if each type of data, viewed in isolation, was not sufficient to prove that Bendectin caused birth defects, then all of them taken together could not prove it either. In so doing, the trial court erred [by granting defendant's motion for J.N.O.V.].

Oxendine, 506 A.2d at 1104. The *Oxendine* court viewed the recalculations of epidemiological studies and the varying conclusions as involving a "classic battle of the experts." *Id.* at 1110. The court refused to find that plaintiffs had provided insufficient evidence to support the jury verdict solely because they had not provided a single original or recalculated epidemiological study which showed a statistically significant association between Bendectin and birth defects. *Id.* at 1107-10.

Oxendine is definitely in the minority camp. Although there appears to be no Ninth Circuit authority directly applicable to these Bendectin cases, this court must view the authority developed by three other federal circuit courts in *Brock*, *Lynch* and *Richardson* as highly persuasive.

In this case, the plaintiffs offer the opinion testimony of eight experts to establish that Bendectin is a teratogen (it causes limb reduction defects generally), and that Bendectin ingested by the mothers during pregnancy caused the limb reduction defects suffered by the infant Daubert and Schuller plaintiffs. Those experts are Dr. Adrian Gross, Dr. Stuart Newman, Dr. Alan K. Done, Dr. Shanna Swan, Dr. Jay Glasser, Dr. Wayne Snodgrass, Dr. Johannes Thiersch and Dr. John Palmer. Plaintiffs have submitted this testimony in the form of affidavits, deposition transcripts, and transcripts from previous trials.

Dr. Adrian Gross is a licensed and accredited veterinarian with experience in pathology and toxicology. *Ealy v. Richardson-Merrell* transcript, Exhibit 26 at pages 650-60. Dr. Gross would testify at trial that to within a reasonable degree of certainty Bendectin is a teratogen. Dr. Gross would base his opinion on animal studies which allegedly show a statistically significant association between Bendectin and doxylamine succinate (a component of Bendectin) and birth defects. *Id.* at pages 834-38.

Dr. Stuart Newman is a specialist in developmental biology. *Ealy* transcript, Exhibit 21 at pages 198-203; *Newman Affidavit* at pages 1-6. Dr. Newman would testify at trial that to within a reasonable degree of certainty "Bendectin is capable of interfering with the development of the limb in the human being and causing birth defects in the developing limb of the human being and that Bendectin is a human teratogen in the normal therapeutic dose." *Newman Affidavit* at page 9. Dr. Newman would base his opinion on *in vitro* studies and the pharmacology aspects of Bendectin. *Id.*

Dr. Alan Done is a medical doctor with specialties in pediatrics, clinical pharmacology and toxicology. *Oxendine v. Richard-Merrell* transcript, Exhibit 31 at page 3. Dr. Done's profferred testimony is unclear from the materials presented, but he apparently would testify that to a reasonable degree of certainty Bendectin is a teratogen. *Id.* at 854. Dr. Done apparently would base his opinion on analyses of the chemical structure and properties of doxylamine succinate animal studies *in vivo*, *in vitro* studies, and various informal and formal human studies, including epidemiological ones. *Id.* at 853.

Dr. Shanna Swan is an epidemiologist and biostatistician practicing in the field of reproductive epidemiology. *Ealy* transcript, Exhibit 12 at pages 3523-27. Dr. Swan would testify that to a reasonable degree of certainty, it is her opinion "that considering all available data that is provided in animal, *in vitro* and epidemiological studies, including the relative risks, the confidence limits and also the power of the studies, that it is more likely than not that Bendectin is, in fact, associated with limb reduction defects." *Swan Affidavit* at page 7. Dr. Swan would base her opinion on "the methodology that is generally and reasonably relied upon by epidemiologists to analyze, study and interpret data that has been collected, published and unpublished in trying to draw opinions concerning whether or not there is a cause and effect relationship between a drug and a birth defect." *Id.* at page 7-8.

Dr. Jay Glasser is a specialist in biostatistics, epidemiology

and biometry. *Hill v. Merrell Dow* transcript, Exhibit 32 at pages 4-7; *Glasser Affidavit* at pages 1-4. Dr. Glasser would testify that "Bendectin is within a reasonable degree of epidemiological certainty associated with congenital disorders, including limb defects." *Glasser Affidavit* at page 7. Dr. Glasser would base his opinion on techniques that are generally and reasonably relied upon by biometrists, epidemiologists and biostatisticians. *Id.*

Dr. Wayne Snodgrass is an associate professor of pediatrics and pharmacology and toxicology. *Rudell v. Merrell Dow* transcript, Exhibit 20 at page 2. Dr. Snodgrass would testify that in his opinion Bendectin is a human teratogen. *Id.* at page 4. Dr. Snodgrass would base his opinion on results of various studies in several disciplines including pharmacology, toxicology, *in vitro* studies, animal studies and human studies. *Id.*

Dr. Johannes Thiersch is a specialist in pathology and pharmacology. *Thiersch Curriculum Vitae*, Exhibit 18. Dr. Thiersch would testify that the chemical composition and physiological activity of a drug are of great interest and importance in determining whether a drug is a teratogen. *Ealy v. Richardson-Merrell* transcript, Exhibit 22 at page 1596.

Dr. John Palmer is a professor of pharmacology. *Palmer Affidavit* at pages 1-4. Dr. Palmer would testify that in his opinion to a reasonable medical and scientific certainty Bendectin is a teratogen. *Id.* at page 7. Dr. Palmer would base his opinion on the pharmacological data, animal studies data, *in vitro* studies data, epidemiological data and other human data. *Id.* at pages 5-7. Dr. Palmer would also testify that he has examined the medical records of the plaintiff children and to a reasonable degree of medical certainty Bendectin was taken at a period of time such as to effect their development and it indeed caused their limb defects. *Id.* at pages 7-8.

The federal courts have held that epidemiological studies are the most reliable evidence of causation in this area. Accordingly, expert opinion which is not based on epidemiological evidence is not admissible to establish causation because it lacks the suffi-

cient foundation necessary under FRE 703. *See, Brock*, 874 F.2d at 311-15; *Richardson*, 857 F.2d at 829-32; *Lynch*, 830 F.2d at 1194. Therefore, expert testimony concluding that Bendectin causes limb reduction defects which is based upon *in vitro* generally studies, chemical structure analyses and animal studies is insufficient to take the issue to the jury. The plaintiffs' experts must be competent to testify that some epidemiological study or recalculation shows a statistically significant relationship between the ingestion of Bendectin and birth defects and that this study forms the basis of their opinion. *Id.* In this case, the plaintiffs have failed to live up to the *Brock* mandate to provide some epidemiological evidence to support their claim that Bendectin is a teratogen. *Brock*, 874 F.2d at 315.

The defendants have introduced evidence that no epidemiological study ever performed has concluded that the use of Bendectin by pregnant women has a statistically significant association to birth defects in those women's children. *Report on the Safety of Bendectin/Diclectin for Use in the Management of Nausea and Vomiting of Pregnancy*, Exhibit J, Defendant's Reply to Affidavits of Plaintiff's Experts Submitted in Opposition to Defendant's Motion for Summary Judgment, at page 2 ("Controlled studies involving over 130,000 patients have not demonstrated any reproducible or consistent association of birth defects with Bendectin exposure. In fact, the results of the epidemiological studies are just what one might expect of an agent without reproductive or teratogenic risks."). *See also Statement of Steven H. Lamm*, Exhibit A, Defendant's Memorandum of Points and Authorities in Support of its Motion for Summary Judgment on the Issue of Causation at page 1 (after reviewing the world's literature on Bendectin and human birth defects, the studies "showed no difference in the risk of birth defects between those infants whose mothers had taken Bendectin during the first trimester of pregnancy and those infants whose mothers had not"). The plaintiffs' experts agree that none of the *published* studies show a statistically significant association between the use of Bendectin and birth defects. *See, e.g., Hill v. Merrell Dow Deposition of Jay H. Glasser*, Exhibit J, Defendant's Memorandum of Points and Authorities in Support of its Motion for Summary Judgment on the Issue of Causation at page 164.

The plaintiffs argue that the absence of statistically significant epidemiological studies does not disprove the fact that Bendectin causes limb reduction defects. *See, e.g.*, Plaintiffs' Opposition to Defendant's Motion for Summary Judgment at 20-27; *Affidavit of Shanna Helen Swan* at pages 4-6. However, this argument directly contradicts the holdings of *Brock, Richardson* and *Lynch*. *See, supra*. The plaintiffs have the burden of proof, and they must come forward with statistically significant epidemiological evidence. The plaintiffs claim that Dr. Gross performed a new epidemiological study on Bendectin, but this is false. He simply recalculated a previously published study and tried to show that there actually was a significant relation between Bendectin and birth defects. *Letter to Thomas H. Bleakley*, Exhibit 40. Dr. Gross' "study" was apparently never published or subjected to peer review, and nowhere does it state that Bendectin sales increased the relative risk of limb reduction defects to a level significantly above 1.0 with a confidence interval that did not include unity. Dr. Gross alleges that this "study" shows "a statistically significant association that is highly significant" (Affidavit at page 11), but his allegation and this evidence is insufficient to take this matter to a jury. *See, Brock*, 874 F.2d at 312-13. Similarly, Dr. Swan's unsupported allegation that the Jick data "statistically significantly associates Bendectin and limb defects" (Affidavit at page 7) is similarly insufficient.

The court feels that the strongest inference to be drawn for plaintiffs based on the epidemiological evidence is that Bendectin could *possibly* have caused plaintiffs' injuries, therefore summary judgment is proper against them. *See, Bieghler v. Kleppe, supra*, 633 F.2d at 533. The court finds that there are no genuine issues of material fact with respect to causation and finds for the defendant on all causes of action.

IT IS SO ORDERED.

Dated: November 1, 1989

APPENDIX C

UNITED STATES COURT OF APPEALS
For the Ninth Circuit

No. 90-55397, D.C. No. CV-84-2013-G(I)

WILLIAM DAUBERT; JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT, a minor; ANITA DE YOUNG, individually, and As Guardian Ad Litem for ERIC SCHULLER,

Plaintiffs-Appellants,

v.

MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation,

Defendant-Appellee.

(Filed April 8, 1992)

ORDER

Before: KOZINSKI and O'SCANNLAIN, Circuit Judges, and MCNAMEE,* District Judge.

The petition for rehearing is denied. The full court has been advised of the suggestion for rehearing en banc and no active judge has requested a vote. The suggestion for rehearing en banc is therefore rejected. Fed.R.App.P. 35(b).

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* The Honorable Stephen M. McNamee, United States District Judge for the District of Arizona, sitting by designation.

No. 92-102

In The

Supreme Court of the United States

October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually, and as Guardian Ad Litem for ERIC SCHULLER,

Petitioners,

vs.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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CORPORATE AFFILIATIONS OF RESPONDENT

Respondent, Merrell Dow Pharmaceuticals, Inc., is a wholly-owned subsidiary of Marion Merrell Dow Inc., which is approximately two-thirds owned by The Dow Chemical Company. Their subsidiaries and affiliates which have securities in the hands of the public are the following:

Arabian Chemical Company Limited

Compagnie des Services Dowell Schlumberger S.A

DCU/LB TRUST

Destec Energy, Inc.

Dexco Polymers

Dow Chemical Iberica S.A.

Transformadora De Etileno S.A.

Chimtrade

Crestar Energy Inc.

Dowell Schlumberger Canada Incorporated

Fort Saskatchewan Ethylene Storage Limited Partnership

U.D. Tech Inc.

Wabiskaw Explorations Ltd.

Cromarty Petroleum Company Limited

Petroquimica-Dow S.A.

Ulsan Pacific Chemical Corporation

Expoxital S.R.L.

Safechem Umwelt Service GmbH

DowBrands L.P.

Dow Corning Corporation

Dowell Schlumberger Corporation

Dowell Schlumberger Inc.

Fort Saskatchwan Ethylene Storage Corporation

Promix System

Dow Kakoh Kabushiki Kaisha

Dow Mitsubishi Kasei Limited

Anticorrosivos Industriales Limitada

Family Comercio e Industria de Produtos de Limpeza Ltda.

Dow-United Technologies Composite Products Inc.

El Dorado Terminals Company

Gurit-Essex A.G.

Etoxilados del Plata S.A.

Joliet Marine Terminal Trust Estate

Lucky Epoxy Limited

Marion Merrell Dow K.K.

MDP (Holdings) Ltd.

Tanabe / Marion Partnership

P.T. Pacific Indomas Plastic Indonesia

Airco Generon Systems LP

DH Compounding Company

DowElanco

Dow Elanco B.V.

Elanco Ihara K.K.

P.T. Pacific Chemicals Indonesia

Pacific Chemicals Berhad

Generon Systems

Generon Systems A.G.

Scotdril Offshore Company

SD Group Service Company Limited

Siam Styrene Monomer Company Limited

Siam Synthetic Latex Company Limited

Zhejiang Pacific Chemical Corporation

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APPENDIX

Illustrative Circuit Opinions 1a

INTRODUCTION

Persistence in the pursuit of righteousness is a virtue; in the pursuit of heresy, it is obstinacy. Via their Petition, Petitioners join a long line of litigants who have repeatedly and unsuccessfully invited this Court to overturn the teaching *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) (*"Frye"*), and its progeny which protect judicial factfinders from scientific shamans who, in the guise of their purported expertise, are willing to testify to virtually any conclusion to suit the needs of the litigant with resources sufficient to pay their retainer.[1]

In the opinion below ("Opinion"),[2] the Ninth Circuit Court of Appeals, per Circuit Judge Kozinski, rejected the Petitioners' pleas to be permitted to swim upstream against an overwhelming scientific torrent of consensus that Bendectin does not cause limb reduction birth defects, and affirmed the granting of the motion for summary judgment made by Respondent Merrell Dow Pharmaceuticals Inc. ("Merrell Dow.") As it has consistently in the past, not only in the context of the Bendectin litigation, but in others as well, this Court should deny the Petition simply because the rule in *Frye* protects the process from becoming a spectacle in which paid experts are willing to mouth any expedient phrase,

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1. Petitions for certiorari denied raising similar issues are: *In Re: Agent Orange Product Liability Litigation*, 611 F.Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied sub. nom Lombardi v. Dow Chemical Co.*, 487 U.S. 1234 (1988); *Brock v. Merrell Dow Pharmaceuticals. Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S.Ct. 1511 (1990) (*"Brock"*); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S.Ct. 218 (1989) (*"Richardson"*); *In Re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990), *cert. denied*, 111 S.Ct. 1584 (1991); *Ealy v. Richardson-Merrell Inc.*, 897 F.2d 1159 (D.C. Cir. 1990), *cert. denied*, 111 S.Ct. 370 (1990) (*"Ealy"*); *Christophersen v. Allied Signal Corp.*, 939 F.2d 1106 (15th Cir. 1991) (per curiam), *cert. denied*, 112 S.Ct. 1280 (1991).

2. *Daubert v. Merrell Dow Pharmaceuticals Inc.*, 951 F.2d 1128 (9th Cir. 1991).

without regard to universally recognized scientific truths. In any event, review of this case is not appropriate, since under *Frye* or any other standard, Petitioners' motion would be denied, and the result would therefore be the same.

As Petitioners point out, this Court just rejected a similar invitation to abandon *Frye* in *Christophersen v. Allied Signals Corp.*, 939 F.2d 1106 (5th Cir. 1991) (per curiam) *cert. denied*, 112 S.Ct. 1280 (1991). The Fifth Circuit Court of Appeals considered, *en banc*, whether plaintiff's expert affidavit, opposing a motion for summary judgment, was admissible to support allegations that a fatal malignancy was proximately caused by workplace exposure to allegedly dangerous chemicals used in the manufacture of nickel/cadmium batteries. *Id.* at 1108. The *Christophersen* majority correctly concluded that plaintiff's expert, Dr. Miller, had nothing more than a scientific hunch, shared by no other experts in the field, and unsupported by epidemiological investigation, live animal testing, or *in vitro* testing. *Id.* at 1115. Notwithstanding the sharp division among the circuit judges of the Fifth Circuit, this Court denied review over the dissent of Justice White, joined by Justice Blackmun.[3]

In a Bendectin case, the reasons for denying Supreme Court review are infinitely more convincing than in *Christophersen*. Bendectin, an anti-nausea medicine prescribed for use during pregnancy, is perhaps the most thoroughly investigated drug in history, at least with respect to whether it causes limb reduction birth defects. As the Opinion noted, and as Petitioners do not dispute, thirty published studies, involving over 130,000 patients,

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3. If the passion of the debate among members of an *en banc* panel of a Circuit Court of Appeals positively correlates with a reason for granting a petition for certiorari, as Petitioners imply, then this Petition presents no reason for it to be granted. Indeed, on the Petitioners' Application for Rehearing, and their suggestion for rehearing *en banc*, not a single active judge requested a vote. Nor was any dissent filed to Circuit Judge Kozinski's Opinion. *See* Appendix C to Petition.

have concluded that there is no epidemiological evidence supporting a statistically significant association between Bendectin and birth defects. 951 F.2d 1128, 1129. Further, time and time again federal and state appellate tribunals have affirmed trial court and jury determinations that Bendectin is not a teratogen.[4]

Frye aside, this case is particularly inappropriate for review, since no matter what evidentiary standard is applied, the outcome would be the same. Note that the Opinion expressly states that the Third Circuit Court of Appeals declines to follow *Frye* in the context of a Bendectin case, citing *DeLuca v. Merrell Dow Pharmaceuticals*, 911 F.2d. 941, 955 (3d. Cir. 1990).[5] In *DeLuca III*, the trial judge followed a different standard articulated by the Third Circuit and on remand granted summary judgment to Merrell Dow, holding that plaintiffs' evidence failed to pass the applicable test of admissibility. While there arguably may be a difference in the Circuits as to the standards governing the admission of expert testimony, that issue should not be resolved here, since plaintiffs' evidence on Bendectin is inadmissible under any standard.

Simply put, the heresy advanced by this Petition is that judges and juries should be permitted by the law of evidence to render judgments or verdicts which contradict scientific propositions as

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4. *See Brock; Richardson; Lynch v. Merrell-National Labs.*, 830 F.2d 1190 (1st Cir. 1987); *Ealy; Wilson v. Merrell Dow Pharmaceuticals Inc.*, 893 F.2d 1149 (10th Cir. 1990); *Turpin v. Merrell Dow Pharmaceuticals*, 736 F.Supp. 737 (E.D. Ky. 1990), *aff'd*, 959 F.2d 1349 (6th Cir. 1992) *petition for cert. filed; Lee v. Richardson - Merrell. Inc.*, 772 F.Supp. 1027 (W.D. Tenn. 1991), *aff'd in unreported decision*, 91-5369 (6th Cir. April 22, 1992); *petition for cert. filed.*

5. Three reported decisions comprise the reported history of this litigation. For the convenience of the Court, the opinions shall be referred to hereafter as: *"DeLuca I": DeLuca v. Merrell Dow Pharmaceuticals Inc.*, 131 F.R.D. 71 (D.N.J. 1990); *"DeLuca II": DeLuca v. Merrell Dow Pharmaceuticals. Inc.*, 911 F.2d 941 (3rd. Cir. 1990); and *"DeLuca III": DeLuca v. Merrell Pharmaceuticals, Inc.*, __ F.Supp. __, 1992 WL 94064 (D.N.J.)

elementary, and as widely accepted as the laws of gravity. *Frye* and the *Federal Rules of Evidence* safeguard the judicial process from such absurd results, and it is proper that they do so. This Petition, like the many others before it, should be denied.

STATEMENT OF FACTS

A. History of Bendectin Litigation.

This Court is no stranger to Bendectin and the litigation spawned by its widespread use to provide relief for millions of pregnant women suffering from morning sickness. Notwithstanding Merrell Dow's almost universal success in defending birth defect claims brought on behalf of children whose mothers used Bendectin during pregnancy, the tidal wave of lawsuits has swept the product from the market, denying pregnant women the only effective therapy approved by the Federal Food & Drug Administration.[6]

Aside from the "experts" paid to testify on behalf of Bendectin plaintiffs, the overwhelming consensus of the relevant scientific community is that Bendectin does not cause birth defects. In fact, this medicine has been called the best studied human non-teratogen. Brent, *Bendectin Our Most Famous Tortogen-Litogen And The Best Studied Human Non-teratogen*, 37 Teratology 447 (1988). Perhaps because of early sensationalism surrounding the suspicion that Bendectin was linked to birth defects, it has now become one of the best studied drugs of all time for use in pregnancy. Skolnick, *Key Witness Against Morning Sickness Drug Faces Scientific Fraud Charge*, 263 J.A.M.A 1468, 1469 (March

6. Indeed, the F.D.A. convened a review panel of experts to examine the scientific record and reevaluate Bendectin's safety and efficacy. Despite the controversy swirling around the drug, the panel concluded that the available data demonstrates no association between Bendectin and birth defects. Department of Health & Human Services News, No. P80-45 (October 7, 1980).

16, 1990). Although serious science has established that the Bendectin children are not victims of a teratogen, there are nevertheless casualties of the Bendectin litigation. Because the litigation drove Bendectin off the market, there is now a "significant therapeutic gap" in the treatment of one of the most frequent complications of pregnancy. Ironically, the severe nausea and vomiting that would have otherwise been treated by Bendectin occasionally leads to maternal nutritional deficiencies and nerve damage in the fetus resulting, perversely, in an increased incidence of birth defects. *Id.* at pp. 1469 and 1473.[7]

Bendectin litigation has mirrored the developing scientific agreement surrounding the use of Bendectin. Less than a handful of the more than 2,000 suits filed against Merrell Dow concerning Bendectin were resolved in plaintiff's favor.[8] The consensus arising from the epidemiological studies translated into repeated success for Merrell Dow in Bendectin cases, leading one judge to observe that the purported teratogenicity of Bendectin has been reduced to the status of a perdurable superstition by the world-wide epidemiological investigations. *Richardson v. Richardson-Merrell Inc.*, 649 F.Supp. 799, 802, n. 9 (D.D.C. 1986), *aff'd*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989). Appellate courts have affirmed the exclusion of expert testimony based on unpublished, non-peer reviewed, and non-epidemiological studies leading to summary judgments and directed verdicts in favor of Merrell Dow. *Richardson*, 857 F.2d 823, 825; *Lynch v. Merrell-National Laboratories, Division of Richardson-Merrell Inc.*, *supra*, 830 F.2d 1190 (1st Cir. 1987). So persuasive is the scientific

7. The sordid history of the Bendectin litigation has been reviewed in a well documented discussion in Huber, *Galileo's Revenge*, Junk Science in the Courtroom, Chapter 7, pp. 111-129 (Basic Books 1991).

8. *See generally*, Green, *Expert Witness and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 Northwestern University Law Review 643, 661-668 (1992).

case against Bendectin's alleged role in causing birth defects, that the Fifth Circuit reversed a jury verdict against Merrell Dow, and entered judgment in its favor. *Brock*.[9]

Uniqueness is the most distinguishing feature of the Bendectin litigation. As noted, no other medication intended for use in pregnancy has been so intensely studied for its alleged propensity to cause birth defects. No other series of product liability actions pits a small group of litigant-financed "experts" against a diverse group of disinterested scientific investigators who have published the work of their epidemiological studies which demonstrate a complete lack of a relationship between Bendectin and birth defects in general, and limb reduction defects in specific. The singular nature of the medicine and the litigation spawned by a collection of plaintiffs' lawyers have prompted one commentator to characterize Bendectin as *sui generis*.[10]

B. The Opinion And Its Procedural History.

Before the District Court, Merrell Dow moved for summary judgment, relying upon a showing that no epidemiological study ever performed had concluded that the use of Bendectin by pregnant women has a statistically significant association to limb reduction birth defects in their offspring. The Petitioners' experts agreed that no published study showed a statistically significant association between the use of Bendectin and limb reduction birth defects, and relied instead upon "reanalyzed" data drawn from published studies finding no association between Bendectin and birth defects, which had been twisted by Petitioners' experts to supposedly demonstrate conclusions diametrically opposed to those drawn by their original authors.

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9. The Opinion placed substantial and justifiable reliance on *Lynch*, *Richardson* and *Brock*. 951 F.2d 1128, 1131.

10. Green, *op.cit.* at p. 677.

Judge Earl B. Gilliam focused the issue correctly when he emphasized the primacy of epidemiological evidence in the absence of a scientific understanding of the cause of the birth defects at issue. That is, in the face of the overwhelming scientific concurrence based on epidemiological studies that Bendectin does not cause birth defects, so called "evidence" drawn from non-epidemiologic and non-published sources will not suffice to raise a triable issue.

The propriety of granting Merrell Dow's motion for summary judgment is reinforced when one considers that virtually all of the evidence presented by Petitioners in opposition to Merrell Dow's motion had been scrutinized by other courts which found, as did Judge Gilliam, the evidence lacking.

For example, Drs. Gross, Thiersch, Newman and Swan all presented evidence on behalf of the plaintiff in *Ealy*. In that case, the testimony of these experts was insufficient to contradict the published epidemiological data; the D.C. Circuit reversed the trial judge's denial of judgment n.o.v. and instructed it to enter judgment in Merrell Dow's favor. 897 F.2d 1159, 1164. Drs. Snodgrass and Glasser presented evidence in *Brock*. As was the case in *Ealy*, the Fifth Circuit was unpersuaded, concluding that the testimony of these experts, among others, did not aid the plaintiff in satisfying her burden of proof on causation. 884 F.2d 1066, 1077. Dr. Done's evidence, although unclear, is apparently the same that he presented in *Richardson*, *supra*, and *Lynch*, *supra*, and was most recently considered at length in *DeLuca III*. In each of these cases, Dr. Done's testimony was insufficient to either support a verdict, or raise a triable issue of fact.[11]

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11. Study of *De Luca III* is particularly instructive, since it comes to exactly the same conclusion as did Judge Gilliam, although utilizing slightly different criteria for the admissibility of expert testimony, as set forth in *United States v. Downing*, 753 F.2d 1224, 1236-1237 (3rd Cir. 1985). Under both Rule 702 and Rule 703, *Federal Rules of Evidence*, Dr. Done's testimony was excluded by Judge Brown: "Dr. Done purports to

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Thus, the only unique affidavit before Judge Gilliam was that of Dr. John Palmer. Alone among Petitioners' experts, Dr. Palmer has relied upon the medical records of the plaintiff children and offers to testify that to a reasonable degree of medical certainty Bendectin caused their limb defects. Significantly, however, Dr. Palmer offered no published epidemiological data supporting his conclusions, and Judge Gilliam correctly determined that it was insufficient to raise a genuine issue of material fact with respect to causation.

In affirming the District Court, the Opinion acknowledged the intense scrutiny given to the question of the responsibility of Bendectin for limb reduction defects by the federal courts. The Opinion makes three important points: First, expert testimony based on scientific technique is admissible if it is generally accepted as a reliable technique among the scientific community, relying, ultimately, on the line of cases initiated by *Frye*. Second, unpublished and non-peer reviewed reanalysis of epidemiological studies is not admissible because it is not generally accepted by the scientific community; this is especially so when the reanalysis was generated solely for use in litigation, citing *Brock, Richardson, and Perry v. United States*, 755 F.2d 888, 892 (11th Cir. 1985). Third, as was recognized by *Lynch, supra, Richardson*, and *Brock*, the constellation of Petitioners' evidence, relying as it does on animal studies, chemical studies, and epidemiological reanalysis,

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have taken the numbers he entered in the boxes on his chart from either the underlying studies themselves, or, in the articles where no calculations were made, from his own calculations. In many cases, as previously noted, this is simply not true. . . . In addition, Dr. Done specifically relied upon several types of data experts in the field would not use in forming their opinions: . . . Dr. Done thus has used data upon which no epidemiologist would rely. This is where Rules 702 and 703 intersect. As the Court of Appeals stated: 'If a study's method of data and collection is faulty, it may be that no expert would rely upon the data generated as a basis for drawing any inference about the studied subject.' *De Luca*, 911 F.2d at 955 n. 4." 1992 WL 94064, 19.

provides an insufficient foundation to allow admission of expert testimony that Bendectin caused Petitioners' injuries. Accordingly, the Ninth Circuit affirmed the granting of Merrell Dow's motion for summary judgment.

The Petitioners sought rehearing by the Panel, and by the Ninth Circuit *en banc*. The petition for rehearing was denied, and no active judge requested a vote on the suggestion for rehearing *en banc*. This Petition then followed.

C. Errors In Petition.

For purposes of satisfying the requirements of Rule 15.1, Supreme Court Rules, Merrell Dow draws to the Court's attention the following misstatements of fact in the Petition.

On the fifth page of the Petition, Petitioners state that Merrell Dow conceded the qualifications of the experts, and that one of the experts were qualified in the discipline of dysmorphology. Merrell Dow never conceded the qualifications of the Petitioners' experts, and none of the eight witnesses proffered by Petitioners were qualified in dysmorphology.

On the seventh page of the Petition, the Petitioners assert that the Ninth Circuit declined to review legal arguments concerning Rule 703, *Federal Rules of Evidence*. This statement is plainly false in light of the heavy reliance in the Opinion placed on *Lynch v. Merrell-National Laboratories. Division of Richardson-Merrell, Inc., supra*, 830 F.2d 1190, and *Richardson*, 857 F.2d 823. Both *Lynch* and *Richardson* discuss at length Rule 703, *Federal Rules of Evidence*, and accordingly the Opinion by embracing the reasoning of *Lynch* and *Richardson* did so as well.

SUMMARY OF ARGUMENT

The Petition satisfies none of the special and important reasons articulated by Rule 10.1, Supreme Court Rules, to warrant review on a writ of certiorari. This case and Bendectin litigation to date may be sufficiently unique that it cannot present a proper vehicle through which this Court can articulate legal axioms useful to litigation in other contexts. Accordingly, review by this Court would reach merely academic and episodic issues. *Rice v. Sioux City Memorial Cemetery*, 349 U.S. 70, 74 (1955).

Because of the unique posture of the Bendectin litigation, the purported split between the Circuits, as suggested by the Petition, is nothing more than a semantic abstraction, lacking any practical significance in the resolution of Bendectin cases. The Opinion transgresses no limitation on inherent judicial authority concerning the admissibility of evidence. Further, the Opinion's insistence upon the requirement for peer review is not expressed as a litmus test appropriate for the admissibility of all expert testimony, but rather is a well-considered rule, appropriately fashioned for the narrow and unparalleled circumstance out of the science underpinning the Bendectin litigation. Accordingly, the Petition should be denied.

ARGUMENT

I.

IN THE CONTEXT OF BENDECTIN LITIGATION, ALL CIRCUIT COURTS OF APPEAL REQUIRE THAT EXPERT TESTIMONY SATISFY A THRESHOLD OF RELIABILITY.

The Petition's suggestion of a schism between the Circuit Courts of Appeal on the application of the *Frye* standard is an inquiry better addressed by philology than jurisprudence. In

Bendectin litigation, where the disinterested scientific community universally agrees that Bendectin does not cause limb reduction birth defects, Petitioners' proposition that the *Federal Rules of Evidence* no longer require general acceptance of scientific or experimental technique does not warrant serious consideration. It is, instead, an exercise drawn not upon an earnest debate over the law governing the admissibility of scientific evidence, but rather semantic hair-splitting designed to circumvent almost 80 years of thoughtful doctrine which protects the judicial factfinding process from becoming a scientific mockery.

The suggestion that *Frye* does not survive, or that there is a serious split in the Circuits regarding *Frye*, is premised on a linguistic distinction, which may have significance in other cases, but is entirely academic in Bendectin litigation. Circuits uniformly hold that trial courts must insist upon thresholds of reliability and acceptance of methodology before scientific testimony can be admitted.[12] Similarly, many state courts have found *Frye* useful in distinguishing legitimate science from unscrupulous hucksterism.

The *Federal Rules of Evidence* clearly provide for judicially created doctrines which aid the trial court in evaluating the admissibility of expert testimony. Rule 104(a) entrusts all preliminary questions concerning the admissibility of scientific evidence to the trial court, and expressly frees it from the rules of evidence in making that determination. Rule 403 authorizes the exclusion of evidence if there is a danger of confusion of the issues or misleading the jury. The teaching in *Frye*, and the other opinions which insist upon the satisfaction of thresholds of reliability as a prerequisite to the admissibility of expert testimony do nothing more than supply the analytic tools for evaluating proffered scientific evidence pursuant to the mandate of Rules 104(a) and 403.

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12. For Circuit opinions illustrating the uniformity of this doctrine, *see* Appendix, *infra*.

That this so-called split between the Circuits is nothing more than theoretical speculation is aptly illustrated by the practical application of the two dominant and purportedly competing standards: *Frye* and *Downing v. United States, supra.* As the Opinion notes, *Frye*, and its Ninth Circuit corollary, *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985), compel the conclusion that the Petitioners' proffered expert testimony be excluded. *Downing* requires exactly the same result as demonstrated by the District Court opinion in *DeLuca III*.

The Third Circuit reversed and remanded a prior ruling granting Merrell Dow's motion for summary judgment, instructing the District Court to reevaluate the plaintiff's evidence under *Downing*. *DeLuca II*, 911 F.2d 941, 955 (3rd Cir. 1990). Following a hearing held on five separate days, extensive post-hearing submissions of the parties, the District Court, applying the *Downing* standards, came to exactly the same conclusion as did Judge Gilliam in ruling on Merrell Dow's motion in the instant action. When applied to Bendectin, the *Downing* standard is properly understood as but a more particularized explanation of the more broadly stated *Frye* standard.[13]

At issue in *DeLuca III* was the admissibility of Dr. Done's opinion. Because the District Court could not ascertain Dr. Done's methodology, which could not be replicated, it concluded that it was novel. Dr. Done identified no specialized literature endorsing his methodology. Although Dr. Done had some scientific credentials, he had none in the field upon which he primarily relied in formulating his opinion, epidemiology. Dr. Done presented no evidence that his methodology has been put to *any* non-judicial

13. The *Downing* standard, to be applied in evaluating the reliability and soundness of a particular scientific methodology is: (1) the novelty of the technique in its relationship to more established modes of scientific analysis; (2) the existence of specialized literature; (3) the qualifications and professional stature of expert witnesses; (4) the non-judicial uses to which the scientific techniques are put; and (5) the frequency with which a technique leads to erroneous results. 753 F.2d 1238-1239.

use; rather, it was formulated exclusively for litigation purposes. The District Court found that his epidemiologic methodology yielded erroneous results so frequently that it is not helpful to the trier of fact. Applying all of the *Downing* factors, the District Court concluded that his methodology was both novel and unreliable, and relied upon only in litigation context. (*See also, Perry v. United States, supra,* 755 F.2d 888, 892 (11th Cir. 1985) ("The examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or medicine.")).

Perhaps those trained in metaphysics will find the distinctions in the application of the *Frye* standard or the *Downing* standard intriguing; in Bendectin cases to date there has not been a bit of difference between them. If this Court is some day inclined to consider whether the Circuits are split on the issue of threshold reliability for the admission of expert testimony, it should consider the matter in a context where the so-called competing formulae make a difference, not in the context, such as is presented with Bendectin, where no matter what slant is put on the problem, the outcome is the same.

Contrary to Petitioners' suggestion, study of *United States v. Jakobetz*, 955 F.2d 786 (2nd Cir. 1992), concerning DNA identification evidence, provides no instruction as to the wisdom of granting the Petition. It is true that the Second Circuit criticizes *Frye*, and observes that it had abandoned it in favor of the approach expressed in *United States v. Williams*, 583 F.2d 1194, 1198 (2nd Cir. 1978), *cert. denied*, 439 U.S. 1117 (1979). But analysis of the *Jakobetz* opinion teaches first that general acceptability is an important analytic tool in applying the *Williams* test, and second that the application of the *Williams* test to Bendectin would lead to exactly the same conclusion as the application of *Frye* or *Downing*.[14] The Second Circuit observed that within the *Williams*

14. The *Williams* factors to be utilized in determination of threshold reliability are: (1) the potential rate of error; (2) the existence and maintenance of standards; (3) the (Cont'd)

guidelines, general acceptability may be indicative of reliability and consequent probative value of the evidence. 955 F.2d 786, 796. The District Court in *Jakobetz* also relied upon whether the technique had been generally accepted by experts in the field before permitting the evidence to be admitted. *Id.* at 797. Lastly, the Second Circuit observed that the careful scrutiny by the District Court of the proffered evidence would satisfy not only *Williams*, but *Frye* as well. *Id.* at 799.

One cannot seriously entertain the suggestion that the application of the *Williams* standards would lead to a different result in a Bendectin case. This is especially true with respect to the risk of abuse standard. The scientific technique of unpublished result-oriented reanalysis of published epidemiological data to reach conclusions contrary to those found by the study's original authors would lend itself manifestly to abuse by credentialed hired guns willing to testify to any opinion convenient to the cause of their employer.

Chief Justice Taft cautions that the power of review on certiorari should be limited to cases where there is a real and embarrassing conflict of opinion and authority between the Circuit Courts of Appeal. *Layne & Bowler Corporation v. Western Well Works*, 261 U.S. 387, 392-393 (1923). As the foregoing illustrates, the Petitioners suggested conflict between the Circuits has no real significance in a Bendectin case. Each standard, whether *Frye*, *Downing*, or *Williams*, have at their root a basic screening function to protect the jury from confusing and misleading evidence,

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care and concern with which a scientific technique has been employed, and whether it appears to lend itself to abuse; (4) the existence of an analogous relationship with other types of scientific techniques and results that are routinely admitted into evidence; and (5) the presence of "fail safe" characteristics or the likelihood that potential inaccuracies will redound to the defendant's benefit rather than his detriment. *Williams*, 583 F.2d 1194, 1198-99, cited in *Jakobetz*, 955 F.2d 786, 794.

pursuant to the mandate of Rule 403, *Federal Rules of Evidence*. Just as all roads led to Rome, so do all of these variations on a theme lead to the same conclusion: In Bendectin litigation, expert testimony, unsupported by published epidemiological data, must be excluded.

II.

THE OPINION DOES NOT OFFEND ANY LIMITATION ON INHERENT JUDICIAL POWER REGARDING THE ADMISSIBILITY OF EXPERT TESTIMONY.

The Petition conjures up the specter of a judiciary run amok, capriciously ignoring the *Federal Rules of Evidence* and arbitrarily erecting artificial barriers to the admission of scientifically supportable expert testimony. In so doing, Petitioners misconstrue the Opinion, misread the *Federal Rules of Evidence*, and misunderstand the fundamental role of the trial judge in safeguarding a lay jury from the indefensible speculations of practitioners of mercenary science.

Contrary to the Petitioners' explicit assertion, the *Federal Rules of Evidence* did not abrogate the common law of evidence. Instead, they expressly recognize, through Rule 104(a), *Federal Rules of Evidence*, the duty of the trial judge to regulate the admission of evidence. In the exercise of that authority, the trial court neither abuses its inherent judicial power, nor ignores the substantive rights of litigants in diversity cases.

A. The Federal Rules of Evidence Do Not Abrogate the Federal Common Law.

The assertion that the *Federal Rules of Evidence* wipe clean the slate upon which the common law of evidence was, and is,

written lacks any support. While the rules must be construed like any other statute (*Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163 (1988)), statutory interpretation may not ignore decisional authority.

This Court recognized the viability of doctrines concerning the admission of evidence which antedate the *Federal Rules of Evidence* in *United States v. Abel*, 469 U.S. 45 (1984). Under consideration was the availability of cross-examination for bias under the *Federal Rules of Evidence*, which did not expressly provide therefor. In concluding that the rules were sufficiently flexible to accommodate cross-examination for bias, now Chief Justice Rehnquist cited with approval Cleary, *Preliminary Notes on Reading the Rules of Evidence*, 57 Neb. L. Rev. 908, 915 (1978), which noted that ". . . [i]n reality, of course, the body of common law knowledge continues to exist, though in the somewhat altered form of a source of guidance in the exercise of delegated powers." *Id.* at 51-52. Thus, this Court has expressly acknowledged that authorities such as *Frye*, or other opinions articulating standards for the threshold of reliability for expert testimony, serve to guide trial courts in the application of the *Federal Rules of Evidence*, and do not, as Petitioners suggest, fade into jurisprudential anachronisms.

To apply well-settled standards of statutory construction, it is clear that if a rule reflects legislative intent to change the interpretation of a judicially created concept, Congress must make that intent specific. *Midlantic National Bank v. New Jersey Department of Envtl. Protection*, 474 U.S. 494, 501 (1986); *Harper v. Federal Land Bank of Spokane*, 878 F.2d 1172, 1176 (9th Cir. 1989). The party contending that legislative action changed settled law bears the burden of showing that the legislature intended such a change. *Green v. Bock Laundry Machine Company*, 109 S.Ct. 1981, 1991 (1989). Petitioners took no steps to

sustain this burden before either the District Court or the Ninth Circuit.[15]

In interpreting a statute or rule, the trial court is to consider the enactment in light of judicial concepts existing previously so to interweave new legislative policies with the inherited body of common law principles. *Moragne v. State Marine Lines Inc.*, 398 U.S. 375, 392 (1970); *Estate of Wood v. C.I.R.*, 909 F.2d 1155, 1160 (8th Cir. 1990). This is precisely the proper integration of the axiom expressed in *Frye* with the mandate of Rule 703, *Federal Rules of Evidence*.

Petitioners' citation to *Chambers v. NASCO, Inc.*, 111 S.Ct. 2123 (1991), is especially intriguing when one considers the interplay between the *Federal Rules of Evidence* and the federal common law. In *Chambers*, the majority, per Justice White, noted that the inherent judicial power to govern and regulate the proceedings before it compliments the various rules and statutes enabling the trial court to assess sanctions and penalties for misconduct, rather than having the rules swallow up the inherent power. ("At the very least, the inherent power must continue to exist to fill in the interstices." *Chambers*, 111 S.Ct. at 2134.) This observation echoes holdings of the Circuits regarding the relationship between the common law and the *Federal Rules of Evidence*. *See Werner v. Upjohn Company, Inc.*, 628 F.2d 848, 856 (4th Cir. 1980), *cert. denied*, 449 U.S. 1080 (1981) ("It is clear that in enacting the Federal Rules of Evidence Congress did not intend to wipe out the years of common law development in the field of evidence, indeed the contrary is true. The new rules contain many gaps and omissions and in order to answer these unresolved questions, courts certainly should rely on common law president. See Redden and Saltzburg *Federal Rules of Evidence Manual* 411-

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15. Of course, a fully developed record is essential to the proper exercise of this Court's discretion on certiorari. *Lytle v. Household Mfg. Inc.*, 110 S.Ct. 1331, 1336, n. 3 (1990).

413 (1975).") and *Cann v. Ford Motor Company*, 658 F.2d 54, 60 (2nd Cir. 1981).

Just as this Court recognized in *Chambers*, the complementary, not antithetical, relationship between inherent judicial power and rules governing the exercise of that power, so did the Opinion recognize the like dynamic between the common law of evidence and the *Federal Rules of Evidence*. Far from superseding all that has gone before, the *Federal Rules of Evidence* build upon the carefully constructed foundation of its common law antecedents.

B. The Federal Rules of Evidence Expressly Authorize Reliance On Judicially Created Doctrine Regarding The Inadmissibility Of Evidence.

The drafters of the *Federal Rules of Evidence* appreciated the need for flexibility on the part of the trial court in fulfilling its function as gatekeeper, barring the admission of plainly unreliable or untrustworthy evidence. Rule 104(a), expressly entrusts to the trial court all preliminary questions concerning the admissibility of evidence. As in other instances, the *Federal Rules of Evidence* draw instruction from this Court, which has consistently held that the district court enjoys wide discretion in the determination to admit or exclude expert testimony. *Hamling v. United States*, 94 S.Ct. 2887, 2903 (1974); *Salem v. United States Lines Company*, 82 S.Ct. 1119, 1122 (1962).

Since the *Federal Rules of Evidence* delegates to the trial judge the decision regarding the inadmissibility of evidence, unfettered by rules of evidence, it is clear that *Frye*, and other opinions expressing the requirement that expert testimony satisfy a threshold of reliability before its presentation to a jury, instruct the trial court in the exercise of this important duty. Thus, the *Federal Rules of Evidence* explicitly contemplate reliance on judicially

created doctrine in determining the admissibility of expert testimony.

The synergy of Rules 104(a) and 703 is naturally most frequently addressed in the opinions of district courts. In *Emigh v. Consolidated Rail Corp.*, 710 F.Supp. 608 (W.D. Pa. 1989), the court considered whether opinions of two non-treating physicians were admissible through plaintiff's experts in a Federal Employers' Liability Act suit alleging that decedent's death from lung cancer was due to work related asbestos exposure. In denying the motion for new trial, the court stressed its function under Rule 104(a) to preliminarily evaluate whether the reasonable reliance requirement of Rule 703 had been satisfied:

> However, we do not believe that the reasonable reliance requirement permits a court to relinquish its independent responsibilities to determine if the underlying source meets the most minimum standards of reliability and trustworthiness as a prerequisite to admissibility. See Fed. R. Evid. 104(a), 401, 403. J.Weinstein & M.Berger, *supra* at 703-2527. Although Rule 703 has greatly relaxed the law regarding the type of information on which an expert may base his opinion, it has not gone so far as to eliminate the requirement that an expert ground his opinion on reliable data rather than speculation. *Barrel of Fun, Inc. v. State Farm Fire and Casualty Co.*, 739 F.2d 1028, 1033 (5th Cir. 1984).

Id. at 612.

In considering evidence premised upon scientific technique or

methodology unsuitable for the proffered purpose, Rule 104(a) explicitly sanctions a trial court's dependence on opinions such as *Frye* in order to help it navigate treacherous waters, teaming with the confusing opinions of experts whose work is performed solely for the purposes of litigation. *See also, Stites v. Sunstrand Heat Transfer Inc.*, 660 F.Supp. 1516, 1523 (W.D. Michigan 1987) and *United States v. Pryba*, 678 F.Supp. 1225, 1232-1235 (E.D. Va. 1988).

The Opinion correctly, albeit implicitly, recognizes the pivotal role that Rule 104(a) plays when it comes to the admissibility of expert opinion based on scientific technique. It aptly places reliance upon Learned Hand's call for temperance in freely permitting every so-called expert to present his opinion to a lay jury, notwithstanding the fact that his opinion contravenes an essential teaching of his scientific community, and was created only due to the generosity of the litigant's subsidy:

> The serious objections are, first that the expert becomes a hired champion of one side. . . .
>
> Enough has been said elsewhere as to the natural bias of one called in such matter to represent a single side and liberally paid to defend it. Human nature is too weak for that; I can only appeal to my learned brethren of the long robe to answer candidly how often they look impartially at the law of a case they have become thoroughly interested in, and what kind of experts they think they would make, as to foreign law, in their own cases.

Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 Harvard Law Review 40, 50-53 (1902).

Far from proscribing judicial reliance upon the test expressed

in *Frye* and its progeny, the *Federal Rules of Evidence* instead encourage judicial use of such doctrines to help lead trial courts through the seemingly impassible maze of credentials, opinions, and unbridled self-interest that inevitably confounds the fact-finder in its weighing of expert testimony.

C. The Issues Addressed In Justice Kennedy's Dissent In Chambers Are Not Presented By The Petition.

In his dissent in *Chambers v. NASCO, supra*, 111 S.Ct. 2123, 2141, Justice Kennedy criticized the majority for failing to require adherence to express (whether via rule or statute) sanctioning provisions before reliance on inherent judicial power in assessing penalties against litigants and their counsel. Justice Kennedy's concern focused on judicial usurpation of both congressional rule making prerogative and state autonomy.

The Opinion offends none of the interests Justice Kennedy seeks to protect. As discussed above, the *Federal Rules of Evidence* expressly provide for the exercise of judicial judgment in the determination of preliminary facts governing the admissibility of evidence. Judicially-created doctrine requiring thresholds of reliability to be satisfied before the admission of expert testimony based upon unaccepted scientific methodology is entirely consistent with the general allocation of responsibility under the *Federal Rules of Evidence*.

The objective of *Erie Railroad v. Tompkins*, 304 U.S. 64 (1938), is to discourage forum shopping and avoid inequitable administration of the laws. *Hanna v. Plumer*, 85 S.Ct. 1136, 1142 (1965). Neither is undermined by the Opinion. Although there may be semantic variations in the expression of the rule requiring that evidence satisfy a threshold of reliability, the bottom line is that all federal courts, following the *Federal Rules of Evidence*, require that such a threshold be satisfied. As *DeLuca III* illustrates, the

result is the same no matter which variation on the theme is applied; plaintiffs in Bendectin actions are unable to raise a triable issue of fact because of the absence of any published epidemiological data suggesting a link between it and limb reduction defects. Similarly, there is no unfairness in the administration of justice, where the outcome is uniform, notwithstanding the particular way in which a court may articulate its insistence that expert testimony be reliable.

The Circuits have consistently recognized that the *Federal Rules of Evidence*, and not the *Erie* doctrine, govern the admissibility of evidence.[16] In *Richardson*, 857 F.2d 823, 825, n. 9 (D.C. Cir. 1988), the D.C. Circuit rejected an argument similar to that advanced by Petitioners, noting that it was clear that *Erie* does not affect the application of the Federal Rules of Evidence, citing *Eli Lilly & Company v. Home Insurance Company*, 794 F.2d 710, 715 (D.C. Cir. 1986), *cert. denied*, 107 S.Ct. 940 (1986), and C. Wright, A. Miller & E. Cooper, *Federal Practice and Procedures* §4512 (1982). The argument was once again rejected in *Ealy*, 897 F.2d 1159, 1163: "Contrary to the Ealys' assertion, however, this court is enforcing a procedural rule governing admissibility; it is not supplanting substantive state rules on the sufficiency of evidence."[17]

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16. This consensus echoes this Court's observation in *Hanna v. Plumer, supra*, 85 S.Ct. 1136, 1143-1144: "The Erie rule has never been invoked to void a Federal Rule. ... When a situation is covered by one of the Federal Rules, the question facing the court is a far cry from the typical, relative unguided Erie choice: The court has been instructed to apply the Federal Rule, and can refuse to do so only if the Advisory Committee, this Court, and Congress erred in their *prima facie* judgment that the Rule in question transgresses neither the terms of the Enabling Act nor constitutional restrictions. (Footnotes omitted.)"

17. This Court has denied repeated petitions for certiorari on the issue of the relationship between *Erie* and the *Federal Rules of Evidence*. *Eli Lilly & Company v. Home Insurance Company, supra*, 794 F.2d 710 (D.C. Cir. 1986), *cert. denied*, 107 S.Ct. 940 (1987); *United States v. Frazin*, 780 F.2d 1461 (9th Cir. 1986), *cert. denied*, *Miller v. United States*, 107 S.Ct. 142 and 107 S.Ct. 158 (1986); *Phillips Oil Co. v. O.K.C. Corp.*, 812 F.2d 265 (5th Cir. 1987), *cert. denied*, 108 S.Ct. 152 (1987).

California courts would not reach a different conclusion. The California Supreme Court has consistently relied upon *Frye* and has used it to exclude methodology not general accepted in the scientific community. *Huntingdon v. Crowley*, 64 Cal.2d 647, 656, 414 P.2d 382 (1966). Petitioners' citations to *People v. McDonald*, 37 Cal.3d 351 (1984); *People v. Pitts*, 223 Cal.App.3d 606 (1990); and *McCleery v. City of Bakersfield*, 170 Cal.App.3d 1059 (1985) are not germane. In each case, the mechanism of the particular phenomenon at issue was explained by the expert testimony. For example, in *McDonald* the expert testimony concerned psychological underpinnings of cross-racial identification. In the Bendectin litigation, however, the mechanism of how many birth defects occur is not known; hence, science is dependent upon epidemiology to confirm a causative link between an environmental factor (such as a medicine prescribed during pregnancy) and the defect. The California Supreme Court notes that when the scientific method is unproven, and ultimately unfounded, California courts are not constrained to admit testimony based upon it, simply because it is expressed by a witness with an academic pedigree. *People v. Shirley*, 31 Cal.3d 18, 53 (1982).

III.

THE OPINION'S INSISTENCE ON PEER REVIEW DOES NOT ABUSE JUDICIAL AUTHORITY.

The Petition criticizes the Opinion for a supposed judicially imposed requirement that renegade reanalysis of epidemiological data be subjected to peer review as a predicate to admissibility. In the unique circumstances of the Bendectin litigation, this condition is one of the few barriers that protects a jury from the unprincipled opinions of any venal technocrat willing to trade his credentials and opinions for whatever fee the market will bear. Especially when a disputed expert opinion bucks a nearly universal scientific consensus, the insistence upon peer review preserves the integrity

both of the trial, and the science there presented.[18]

Focus on what the Bendectin litigation is, and what it is not. The controversy surrounding Bendectin does not pit two schools of reputable scientific thought against one another, equally supported by independent sets of data, separately derived by disinterested observers. Rather, on one side of the Bendectin Armageddon is an array of independent scientific investigators who, via epidemiology, have scrutinized from 1976 to the present whether Bendectin causes limb reduction birth defects; without exception these investigators, despite every incentive to find a link between this popularly prescribed drug and birth defects, found absolutely none. This side of the struggle has consistently published, subjecting all of the data to the strictest standards of peer review. Lined up against these forces are a combination of doctors (medical and otherwise), veterinarians, and one epidemiologist, whose sole common denominator is that they have been retained by plaintiffs' attorneys representing clients alleging injuries due to exposure to Bendectin.[19] None of their work has been published, or

18. In the area of expert testimony, the requirement for peer review is invaluable. One cannot help but be reminded of Learned Hand's recognition that without such protections as peer review, a jury is unable, and indeed incapable to discern scientific truth from scientific fraud: "The trouble with all this is that it is setting the jury to decide, where doctors disagree. The whole object of the expert is to tell the jury, not facts, as we have seen, but general truths derived from this specialized experience. But how can the jury judge between two statements each founded upon an experience confessedly foreign in kind to their own? It is just because they are incompetent for such a task that the expert is necessary at all." *Hand, op.cit.*, at 53; cited in *Christophersen v. Allied-Signal Corp., supra*, 939 F.2d 1106, 1112.

19. In fact, Dr. Shanna Swan, the only epidemiologist retained on behalf of the petitioners, testified:

> Q. In fact, the reanalysis that you did was funded by plaintiffs' lawyers suing Merrell Dow; isn't that correct?
> A. That is correct and I should add that I so stated both times I presented the paper.

C.R. 162 Exhibit "12", Shanna Swan Trial Testimony, *Ealy v. Richardson-Merrell Inc.*, p. 3540, l. 20 - p. 3541, l. 3.

subjected to peer review; furthermore, all of their data is produced through unreliable scientific technique, which often cannot be replicated, performed at the request of litigants whose undisputed interest lies in finding a causative link between Bendectin and congenital abnormalities.

Under these circumstances, peer review and publication insulate the jury from the expert opinion formulated solely to satisfy the interests of those who paid for it. This protection is necessary because of the aura of apparent objectivity that surrounds scientific inquiry. Testimony that claims a scientific basis may carry undue weight with the trier of fact. *Sterling v. Velsicol Chemical Corp.*, 855 F.2d 1188, 1208 (6th Cir. 1988); *United States v. Brown*, 557 F.2d 541, 556 (6th Cir. 1977).

Petitioners suggest that far from being salutary, peer review is actually a device through which small-minded, conceited and jealous journal editors unfairly regulate the dissemination of scientific investigation. Before neither the District Court, nor the Ninth Circuit did Petitioners make any showing that the research upon which their champions rely suffered this fate. Instead, Petitioners apparently feel it is appropriate for this Court to judicially notice that peer review is the functional equivalent of some scholarly inquisition to burn the heretic and reward the devout.

In fact, peer review is far from an elitist barrier to the free flow of important scientific insights. It is considered vital to both scientific integrity and progress (Lock, "The State of Peer Review," *Peer Review and Scientific Publishing*, Council of Biology Editors, Inc., p. 30 (1990)). One author has written that it would be hard to imagine how society would get along without peer review. Relman, "How Good Is Peer Review," *New England Journal of Medicine*, Vol. 321, No. 12, p. 827 at 829. Stephen Lock, the editor of the British Medical Journal, explained the role of peer

review in the field of scientific inquiry in *A Difficult Balance*, Editorial Peer Review in Medicine (1985). He emphasizes that in order to be reliable, empirical observations and scientific theories must survive critical study in testing by other competent and disinterested people, and that publication plays a key part in this role. *Id.*, 1. Through the rigors of peer review, diagnostic standards for causation have been embraced by the scientific community. Included in these standards are such inquiries as: "Do other investigators consistently find the same result?" and "Does the association make epidemiological sense?" *Id.*, 118.

The antithesis of these rigorous epidemiological standards is, Dr. Lock has noted, a phenomenon called "pathological science," which has as its hallmark features present in the proffered testimony of the Petitioners' experts. *Id.*, 76-77. Among these characteristics are whether many measurements are necessary because of the very low statistical significance of the results, and whether the ratio of supporters to critics gradually falls to nil over time. Only through extensive, result-oriented reanalysis of published epidemiological data are the Petitioners' experts able to fashion any epidemiological inference regarding causation. Petitioners acknowledge that there are no peer reviewed published supporters of the hypothesis that Bendectin causes limb reduction defects.

Dr. Lock should not be understood as advocating the perfection of editorial peer review. However, he does maintain that it plays an essential role in medicine and science, since it is the best way of distinguishing between the promising and the meretricious. *Id.*, 129.

When confronted with a battle of peer reviewed vs. nonpeer reviewed experts, most courts choose the former and dismiss the latter. Consider, for example, *In Re Air Crash Disaster at New Orleans La.*, 795 F.2d 1230 (5th Cir. 1986), a wrongful death

action in which the verdict for the plaintiff was reversed because of the inherently incredible testimony of an economist on the issue of an anticipated inheritance:

> We know from our judicial experience that many such able persons present studies and express opinions that they might not be willing to express in an article submitted to a refereed journal of their discipline or in other contexts subject to peer review. We think that is one important signal, along with many others, that ought to be considered in deciding whether to accept expert testimony. Second, the professional expert is now commonplace. That a person spends substantially all of his time consulting with attorneys and testifying is not a disqualification. But experts whose opinions are available to the highest bidder have no place testifying in a court of law, before a jury, and with the imprimatur of the trial judge's decision that he is an "expert".

Id. at 1234.

The importance of peer review has been stressed in a number of contexts outside the ambit of Bendectin litigation. *See In Re Agent Orange Product Liability Litigation, supra*, 611 F.Supp. 1223, 1242 (E.D.N.Y. 1985), *affirmed on other grounds*, 818 F.2d 187 (2d Cir. 1987), *cert. denied, sub. nom Lombardi v. Dow Chemical Company*, 487 U.S. 1234 (1988); *Kubs v. United States*, 537 F.Supp. 560, 562 (E.D. Wis. 1982); *Kilburn v. United States*, 938 F.2d 666, 673 (6th Cir. 1991).

The Opinion properly relies upon the requirement for peer review expressed in the reported decisions of sister circuits. For

example, in *Richardson*, 857 F.2d 823 (D.C. Cir. 1983) the D.C. Circuit affirmed the granting of judgment notwithstanding the verdict, noting:

> The district court observed that Dr. Done had performed none of his own studies nor published his criticisms of the studies performed by others, but nonetheless testified in contradiction to 'not only Dr. Seltser (defendant's expert) but to the findings of all those researchers who have studied and published in the 20 odd years since the investigation of Bendectin began.'

Id. at 826. The *Richardson* opinion goes on to observe that uniquely in the context of Bendectin litigation, the law now has the benefit of 20 years of scientific study, and the published results of such work must be given their just due. *Id.* at 832.[20]

In *Lynch v. Merrell-National Laboratories, supra*, 830 F.2d 1190, 1194 (1st Cir. 1987), the summary judgment in favor of the defendant was affirmed, just as it was in this case:

> The first (epidemiologic studies) began in 1963; studies are still being published in 1986. No correlation, much less a causal connection, has been demonstrated between the use of Bendectin and limb reduction. . . . A new study coming to a different conclusion in challenging the consensus would be

20. *Accord, Ealy*, 897 F.2d 1159, 1162. ("Unlike the circumstances of *Ferebee* [*v. Chevron Chemical Company*, 736 F.2d 1529 (D.C. Cir. 1984)], the body of *published* epidemiological opinions on the subject at hand is extensive, indeed massive, and all such opinions point to the same conclusion.")

> admissible evidence. Without such a study, there is nothing on which expert opinion on Bendectin as a cause may be based. The plaintiffs offered no new study.

Id. at 1193-1194.

In *Brock*, 874 F.2d 307 (5th Cir. 1989), the Fifth Circuit criticized plaintiff's biostatistics expert because he had not published his opinion or conclusion for the purposes of peer review. The opinion counseled that courts must nonetheless be especially skeptical of medical or other scientific evidence that has not been subjected to thorough peer review. *Id.* at 313.

The Petition falsely implies that the Opinion artificially bars unorthodox but unpublished scientific theories from the courtroom. The Opinion holds that when published data is to be reanalyzed for litigation to reach a result antithetical from that intended by its authors, then that reanalysis must be peer reviewed to be admissible. This result is sound, consistent with long-standing authority, and does not warrant further review or comment by this Court. As discussed above, the *Federal Rules of Evidence* expressly provide for the exercise of judicial judgment in the determination of preliminary facts governing the admissibility of evidence. Judicially created doctrine requiring thresholds of reliability to be satisfied before the admissibility of expert testimony based upon scientific methodology not widely accepted in the scientific community is entirely consistent with the general allocation of responsibility under the *Federal Rules of Evidence*.

CONCLUSION

The Petition should be denied. The energies of this Court should only be marshalled to consider issues of broad application. The stage on which the Bendectin litigation is played out is peculiar to itself; no other theater presents a drama where the line between fact and illusion is so clearly drawn. Only Bendectin plaintiffs and their expert footmen resist that concurrence of the scientific community that Bendectin does not cause limb reduction birth defects. The Circuits uniformly require that expert testimony satisfy a threshold of reliability; no matter how that threshold is articulated, the expert testimony proffered by Petitioners cannot pass muster. Rules relied upon in Bendectin litigation are sound in that context, but not necessarily so in all others. Scrutiny by this Court of these issues is unwarranted.

Respectfully submitted,

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APPENDIX - ILLUSTRATIVE CIRCUIT OPINIONS

FIRST CIRCUIT: *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190, 1194-95 (1st Cir. 1987) (expert testimony inadmissible after a critical analysis of experts' methodologies and the lack of peer review of proffered studies).

SECOND CIRCUIT: *United States v. McBride*, 786 F.2d 45, 49 (2nd Cir. 1986) ("expert testimony must be based upon a reliable area of expertise, as has come to be embodied in the rule associated with *Frye v. United States*.") But *cf. United States v. Williams*, 583 F.2d 1194 (2nd Cir. 1978), *cert. denied, Williams v. United States*, 439 U.S. 117 (1979) and *United States v. Jakobetz*, 955 F.2d 78 (2nd Cir. 1992).

THIRD CIRCUIT: *DeLuca v. Merrell Dow Pharmaceuticals Inc.*, 911 F.2d 941, 956 (3rd Cir. 1990) ("The district court is permitted to identify relevant scientific communities and make determinations about the degree of acceptance of [plaintiff's experts] methodology within those communities"). It should be noted that although the Third Circuit does not follow *Frye*, the difference between its test and *Frye* is explained in the Third Circuit opinion in *United States vs. Downing*, 753 F.2d 1224, 1238. "The reliability inquiry that we envision is flexible and may turn on a number of considerations, in contrast to the process of scientific 'nose-counting' that would appear to be compelled by a careful reading of *Frye*."

• • •

"Thus, we expect that a technique that satisfies the *Frye* test usually will be found to be reliable as well. On the other hand, a known technique which has been able to attract only minimal support within the community is likely to be found unreliable.").

Appendix

FOURTH CIRCUIT: *Ellis v. International Playtex Inc.*, 745 F.2d 292, 304 note 15(4th Cir. 1984) (continuing to recognize the validity of the *Frye* test).

FIFTH CIRCUIT: *Christopherson v. Allied Signal Corp., et al.*, 939 F.2d 1106 (5th Cir. *en banc* 1991), *cert.denied*, 112 S.Ct. 1280 (1992) (District Court was within its discretion in concluding, albeit implicitly, [the experts] testimony failed to meet . . . the *Frye* test.)(The *Federal Rules of Evidence* combined with *Frye v. United States*, 293 F. 1013 (D.C.Cir. 1923), provide a framework for trial judges struggling with proffered expert testimony.) *See also, Barrel of Fun Inc. v. State Farm Fire & Casualty Co.*, 739 F.2d 1028 (5th Cir. 1984) (using *Frye* test to hold inadmissible a voice stress analysis process).

SIXTH CIRCUIT: *United States v. Metzger*, 778 F.2d 1195, 1203 (6th Cir. 1985), *cert. denied*, 477 U.S. 906 (1986) ("[this Circuit] still predicate[s] the admission of scientific evidence on general acceptance in the community").

SEVENTH CIRCUIT:*United States v. Smith*, 869 F.2d 348, 351 (7th Cir. 1989) ("this Circuit has continued to affirm (and to apply) the *Frye* standard").

EIGHTH CIRCUIT: *United States v. Two Bulls*, 918 F.2d 56, 60 n.7(8th Cir. 1990) (refusing to reject use of *Fry* in evaluation of "the admissibilily of any questionable opinion evidence").

NINTH CIRCUIT: *United States v. Gillespie*, 852 F.2d 475, 481-82 (9th Cir. 1988) (criminal conviction reversed because testimony of child therapist relating to child's behavior with anatomically correct dolls did not satisfy the *Frye* standard). *See also, Dang Vang v. Vang Xiong X. Toyed*, 944 F.2d 476, 482 (9th Cir.

Appendix

1991) (the Court acknowledged the use of *Frye* in the Ninth Circuit; however, the test was inapposite because the case did not involve novel scientific technique).

TENTH CIRCUIT: *Head v. Lithonia Corp. Inc.*, 881 F.2d 941, 943-44 (10th Cir. 1989) (expert opinion based on topographical brain mapping excluded because technique was relatively experimental and not accepted by the scientific community).

ELEVENTH CIRCUIT: *United States v. Piccinonna*, 885F.2d 1529,1531 & 1536 (11th Cir. 1989) (*Frye* limits, though does not bar, the admission of polygraph evidence in criminal trials).

D.C. CIRCUIT: *Kropinski v. World Plan Executive Council - U.S.*, 853 F.2d 948, 956 (D.C. Cir. 1988) ("We have recently held that *Frye is* still the law in this circuit."(citing *United States v. Shorter*, 809 F.2d 54, 59-61 (D.C. Cir.) *cert. denied*, 484 U.S. 817 (1987)).

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IN THE
Supreme Court of the United States
October Term, 1992

WILLIAM DAUBERT AND JOYCE DAUBERT, INDIVIDUALLY AND AS GUARDIANS AD LITEM FOR JASON DAUBERT, AND ANITA DE YOUNG, INDIVIDUALLY AND AS GUARDIAN AD LITEM FOR ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY TO BRIEF IN OPPOSITION

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REPLY TO BRIEF IN OPPOSITION

Merrell's extravagant verbal invective and *ad hominem* attacks on petitioners' experts cannot obscure the square holding below that federal judges may use the *Frye* test and a related "peer review requirement" to screen and exclude scientific conclusions not "generally accepted" within a judicially defined scientific community. Petitioners and several circuits disagree with the Ninth Circuit's approach and contend that both *ad hoc* tests are foreclosed by the express language and underlying policies of the Federal Rules of Evidence. All three issues posed — the appropriateness of the *Frye* rule, the permissibility of judicial imposition of additional substantive burdens on expert testimony in general, and the permissibility of a "publish-or-perish" peer review requirement under the Federal Rules of Evidence — are cleanly presented, are purely legal in nature, and merit this Court's review.

1. Certiorari is Warranted to Resolve the Circuit Conflict on the *Frye* Issue.

Merrell does not and cannot dispute the existence of a circuit conflict over whether federal judges may use the *Frye* test to screen out expert scientific testimony based on a conclusion that it is not "generally accepted" by the relevant scientific community. Indeed, Judge Becker of the Third Circuit, in a comprehensive discussion of the Federal Rules of Evidence, recently characterized "the standard for admitting novel scientific testimony" as "the most controversial and important unresolved question in the Federal Rules." Becker & Orenstein, *The Federal Rules of Evidence After Sixteen Years — The Effect of "Plain Meaning" Jurisprudence, the Need for an Advisory Committee on the Rules of Evidence, and Suggestions for Selective Revision of the Rules*, 60 Geo. Wash. L. Rev. 857, 863 (1992) (hereinafter "Becker"). *See also id.* at 876-79 (discussing nature of the *Frye* issue).

In March 1992, this Court evidently deemed the Fifth Circuit's decision in *Christophersen v. Allied Signal Corp.*, 939 F.2d 1106 (5th Cir. 1991) (per curiam), *cert. denied*, 112 S.Ct. 1280 (1992), to be an inappropriate vehicle for addressing the *Frye* issue. *See* Pet. 11-13.[1] In the scant six months since then, no fewer than three

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[1] Merrell's Opp. 1 n.1 ignores that "[t]he denial of a writ of certiorari imports no expression upon the merits of the case, as the bar has been told many times," *United States v. Carver*, 260 U.S. 482, 490 (1923), and is factually erroneous.

cases (including this one), all of which are now pending, have been presented to this Court on the *Frye* issue. *See Jakobetz v. United States*, No. 91-7921 (discussed in Pet. 14-16); *45/194 Kg. Drums of Pure Vegetable Oil v. United States*, No. 92-173.[2] Thus, the question for this Court is not *whether* to resolve the *Frye* conflict, but rather *which case* provides the most appropriate vehicle for a clear resolution. The Petition and this Reply demonstrate that this case is an entirely suitable vehicle.[3]

Evidently sensing the futility of completely denying a circuit split regarding *Frye*, Merrell instead claims that review should be denied in *this* case because petitioners allege harm resulting from Bendectin, and "[r]ules relied upon in Bendectin litigation are sound in that context, but not necessarily so in all others." Opp. 30. But Congress has not promulgated special evidence rules for Bendectin cases, and the suggestion that *Frye* might be applicable as a special rule only in Bendectin cases illustrates the *ad hoc* and unprincipled nature of the view underlying Merrell's position and the decision below. Merrell's cavalier claim is incompatible with Congress's central objective in enacting the Federal Rules of Evidence: to ensure the uniform application of evidence law in all federal cases. *See* Pet. 16. Here, "[c]ircuit splits are detrimental because they undermine the goal of uniformity that underlies the enactment of Federal Rules." Becker, *supra*, at 892.

Merrell also opposes review by arguing that, even if this Court were to adopt the approach followed by those circuits which reject *Frye*, the outcome in this case on remand would be the same —

[2] *Frye* was originally used in a limited criminal context, but since the Fifth Circuit's dramatic expansion of the "general acceptance" test to the civil arena in *Christophersen*, *see* Pet. 17 n.5, *Frye* has been applied in a broad variety of cases beyond criminal law. For example, courts have relied on *Frye* to exclude evidence in subject areas as diverse as state products liability law (this case), FDA regulations (*45/194 Kg. Drums of Pure Vegetable Oil*, *supra*), and federal liability under the FELA for injuries to railroad workers (*Eggar v. Burlington Northern R.R.*, 1991 U.S. Dist. LEXIS 19240, *8 (D. Mont. 1991)). Because roughly a third of all cases in the federal courts depend on expert testimony, *see* Imwinkelried, *The "Bases" of Expert Testimony: The Syllogistic Structure of Scientific Testimony*, 67 N.C. L. Rev. 1, 1 (1988), the need for this Court's review of the *Frye* issue is particularly pressing.

[3] If this Court grants review in either of the other two cases, this Petition should at minimum be held pending disposition of the case granted review.

petitioners' expert testimony would be excluded. Opp. 12-14. This analysis is in error for at least three reasons:

First, petitioners do not ask this Court to adopt the law of any particular circuit or to rule on the precise facts of this case. They merely ask this Court to hold that the *Frye* rule was superseded by enactment of the Federal Rules of Evidence, confirming the view of the Solicitor General that Rule 702 "does not . . . suggest that the standard for admissibility of novel scientific evidence should be more stringent than the standard that applies to other forms of expert testimony." *See* Pet. 15-16. This Court need not fear that review would be factually complex; plainly, this Court can determine and articulate the meaning of the Federal Rules without extensive inquiry into the underlying scientific record or specific facts of this case. *See, e.g., Celotex v. Catrett*, 477 U.S. 317 (1986) (setting forth interpretation of Fed. R. Civ. P. 56 without inquiry into the complex record of underlying asbestos litigation).

Second, Merrell's prediction of how petitioners' expert evidence would fare under the current admissibility standards of the three circuits that have rejected *Frye* is both incomplete and totally speculative. The Opposition does not even venture a guess as to the result under the law of the Fourth Circuit, *see* Pet. 11 n.4. Merrell predicts that Second Circuit precedent would not "lead to a different result in a Bendectin case," Opp. 14, even though that Circuit has never addressed such a case.[4] The essential point is that each case will turn on its own facts and evidence; in the absence of *Frye*, there will not be automatic victories for plaintiffs or for defendants.

[4] As to the Third Circuit, which has addressed a Bendectin case, Merrell relies on the narrow and fact-specific holding in a district court remand without any showing of relevance to the instant case. Opp. 12-13. The district court in *DeLuca III* indeed applied the Third Circuit's *Downing* standard to exclude one expert's affidavit concerning Bendectin causation. However, as Merrell candidly notes, the expert in that case had no credentials "in the field upon which he primarily relied in formulating his opinion." Opp. 12. Ruling such testimony inadmissible is an unremarkable application of Rule 702, and it hardly dictates the outcome that would be reached in *this* case under the *Downing* standard. In this case petitioners presented eight highly qualified experts, none of whose qualifications Merrell challenged. (Merrell's statement that it "never conceded the qualifications of Petitioners' experts," Opp. 9, is a play on words; the important and undisputed point is that Merrell declined to challenge these experts' qualifications in its summary judgment motion.) Thus nothing in Third Circuit law requires the inadmissibility of petitioners' expert affidavits in this case.

Third, Merrell completely ignores petitioners' demonstration that, absent its *Frye* analysis, the Ninth Circuit would in fact require admission of petitioners' evidence. The district court utilized Fed. R. Evid. 703 to exclude petitioners' expert testimony because that testimony supposedly was not based on the "most reliable" data. Pet. 6 n.2. Petitioners' expert testimony did rely on "four standard sources of information" (Pet. 5) and, absent *Frye*, Ninth Circuit law does not authorize district judges to insist on the "*most* reliable" sources. Indeed, Merrell does not deny that the Ninth Circuit has consistently read Rule 703 to permit an expert to rely on "'any type of evidence commonly used in the field.'" Pet. 4 & n.1 (quoting *Rogers v. Raymark Industries, Inc.*, 922 F.2d 1426, 1429-30 (9th Cir. 1991)). Thus, if this Court rules against use of the *Frye* test, on remand the Ninth Circuit would have no grounds — on the record of *this* case — to exclude petitioners' evidence.

Although it is in no way necessary for this Court — either at this stage or on the merits — to consider the factual context of the Bendectin litigation, that factual context actually argues *for* review because it illustrates a central criticism of the *Frye* rule. As petitioners have explained without rebuttal, Pet. 11 n.4, one of the chief faults of the *Frye* rule is that it is "too vague and malleable to yield consistent results." *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 955 (3d Cir. 1990). *Frye* allows judges to determine the outcomes of cases by arbitrarily selecting a particular "scientific community" within which there is a "consensus." Using *Frye*, courts may "manipulate the parameters of the relevant 'scientific community' and the level of agreement needed for 'general acceptance'" to reach the results they desire. *United States v. Downing*, 753 F.2d 1224, 1236 (3d Cir. 1985). Worse, courts may accomplish such manipulation without ever engaging in an independent review of the factual record of the underlying claim. For example, the Ninth Circuit below simply relied on previous circuit court decisions involving the admissibility of Bendectin evidence on other records. (A3-A4). Such reliance on earlier cases, rather than on the evidence presented in *this* case, illustrates the Third Circuit's concern that *Frye* leads to an "uncritical acceptance of prior *judicial*, rather than scientific, opinion as a basis for finding 'general acceptance.'" *Id.* at 1236 (emphasis in original).

This case also perfectly illustrates the extreme malleability of the *Frye* rule by demonstrating that a court can construct its own "scientific consensus" simply by selectively excluding entire classes

of scientific data on a given issue. The Ninth Circuit below focused exclusively on epidemiological studies published in peer-reviewed journals. (A3 to A4). Using only these studies, the court determined that there was a "consensus" and that the views of petitioners' experts were not "generally accepted." In order to reach this conclusion, however, the Ninth Circuit was forced arbitrarily to reject animal and chemical studies as "insufficient to establish a link between Bendectin and birth defects." (A3 (citation omitted)).

Yet in another Bendectin case, the Sixth Circuit observed — only three months later — that "[a]nimal studies often comprise the backbone of evidence indicating biological hazards, and their legal value has been recognized by federal courts and agencies." *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (6th Cir. 1992). Moreover, far from finding a "consensus" on Bendectin based on the extant epidemiological studies, the Sixth Circuit found that Merrell "overstates the power of these statistical studies," that Merrell's studies are "by no means conclusive," and that "[a]n analysis of this evidence demonstrates that it is possible that Bendectin causes birth defects even though these studies do not detect a significant association." *Id.* at 1357.[5] The context of this

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[5] Merrell's claim of "consensus arising from . . . repeated success for Merrell in Bendectin cases" is belied by the Sixth Circuit's emphasis on the "inconsistent results" nationwide: although "[f]our federal circuits have held that plaintiffs failed as a matter of law to establish causation," "other courts have either denied or reversed on appeal grants of summary judgment for [Merrell] in eight cases." *Turpin*, 959 F.2d at 1351-52. The lack of a consensus is concretely illustrated by the results of the 1985 multi-district common issues trial that resolved over 800 Bendectin cases, in which the Sixth Circuit observed that "the jury verdict following trial here might have been for the plaintiffs instead of for the defendant." *In re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, 857 F.2d 290, 325 (6th Cir. 1988), *cert. denied*, 488 U.S. 1006 (1989), *aff'g* 624 F. Supp. 1212, 1244 (S.D. Ohio 1985) ("[b]oth sides presented testimony of eminently qualified and highly credible experts who differed in regard to the safety of Bendectin"). Similarly, Chief Judge Rubin, the trial judge in the multi-district case, refused Merrell's request for summary judgment in other individual cases, stating that "the Court is convinced that there are genuine issues of fact which preclude entry of summary judgment." *In re Bendectin Products Litigation*, 732 F. Supp. 744, 749 (E.D. Mich. 1990). *See also Wilson v. Merrell Dow Pharmaceuticals, Inc.*, No. 83-C-710-E, slip op. at 1 (N.D. Okla. March 1, 1990) (finding that "[s]ubstantial scientific evidence exists to support both the conflicting arguments regarding causation"); *Longmore v. Merrell Dow Pharmaceuticals, Inc.*, 737 F. Supp. 1117, 1120 (D. Idaho 1990) (rejecting resort to supposedly "overwhelming" statistical data in order "to bulldoze aside the plaintiffs' experts").

The current status of Bendectin litigation thus reveals a *controversy*, not a "consensus," within the scientific community and the courts on causation.

case thus clearly illustrates the arbitrary results permitted by resort to the *ad hoc Frye* test, and to the extent this Court considers the underlying facts of this case at all, the fact that petitioners' claim involves Bendectin is an argument *for* review rather than against it.

2. Certiorari is Warranted on the Issue of Inherent Judicial Power.

The Ninth Circuit's use of the *Frye* test to screen out novel scientific evidence "is inconsistent with the letter and spirit of the Rules." Becker, *supra*, at 863. The plain language and history of the Federal Rules of Evidence indicate that such judge-made rules for exclusion of evidence are impermissible.

Merrell argues that the Federal Rules of Evidence do not "wipe clean the slate upon which the common law of evidence was, and is, written." Opp. 16-17. But that is a straw man. Petitioners simply maintain that federal courts have no inherent authority to *exclude* evidence that Congress has otherwise deemed admissible. Pet. 17-27. Merrell contends, in effect, that common-law exclusionary rules such as *Frye* haunt the federal courthouses until Congress statutorily exorcises each one, incanting its volume and page number from the Federal Reporter. But this position is not colorable given that Congress specifically listed *all* grounds for excluding evidence in Fed. R. Evid. 402. Pet. 19-20. In any event, Merrell's contention is an argument on the merits that only underscores the seriousness of the need for a definitive holding by this Court.

Although the court below *did not even cite* Fed. R. Evid. 104(a), Merrell — in another argument on the merits — asserts that the Ninth Circuit "correctly, albeit *implicitly*, recognizes the pivotal role that Rule 104(a) plays" in "encourag[ing] judicial use of [common-law exclusion] doctrines [such as *Frye*] to help lead trial courts" in determining the admissibility of scientific testimony. Opp. 20-21 (emphasis added). There are two problems with this argument. First, it was never articulated by the Ninth Circuit below. Second, this Court has squarely rejected any such construction of Rule 104(a). In *Bourjaily v. United States*, 483 U.S. 171 (1987), this Court repudiated the theory that Rule 104(a) provides a blank check for district judges to exclude otherwise admissible evidence using common-law doctrines which antedate the

Federal Rules of Evidence but are not repudiated therein *by name*.[6] Writing for the Court, Chief Justice Rehnquist also held that Congress was not required to issue legislative history confirming that Rule 104(a) means what it says. *See* Pet. 21-22; *cf. Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2618 (1992).

In addition to departing from plain language, the court below enunciated a "general acceptance" standard that operates to extinguish the state-created tort rights of an entire class of litigants throughout the states of the Ninth Circuit. This holding is in clear disregard of this Court's *Erie* jurisprudence. Merrell argues (Opp. 23) — albeit incorrectly, *see* Pet. 25-26 & n.7 — that use of the *Frye* test yields the same result in this case as if it had been tried in California state court. But Merrell ignores entirely the impact of the Ninth Circuit's holding on the substantive law of the *other* states within the Circuit. The Opposition makes no attempt to show that the *Frye* rule embraced below would yield the same results in federal and state courts if an action similar to this case arose under the law of Alaska, Arizona, Idaho, Montana, Nevada, Oregon, or Washington. In fact, *none* of these states employs the substantive *Frye* hurdle, and three of these states have specifically rejected it.[7]

The opinion below thus ensures that cases that would reach trial if heard in state court will be summarily dismissed in federal court under the Ninth Circuit's *Frye* rule. Such disparate results typify inequitable administration of the laws and encourage forum-shopping. In sum, the Ninth Circuit acted without regard or respect

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[6] *Bourjaily* held that Rule 104(a) does not license judges to utilize the common-law "bootstrapping doctrine" to exclude evidence otherwise admissible under the coconspirator exemption to the hearsay rule. Under the common law "bootstrapping doctrine," a coconspirator's statement had to be corroborated by independent evidence of a conspiracy before the statement would be considered admissible (i.e., an exception to the general prohibition on hearsay). Federal Rule of Evidence 801(d)(2)(E), however, mentions no requirement of independent evidence, and this Court held that the plain meaning of the rule forecloses any judicial imposition of such a requirement. *See Bourjaily*, 483 U.S. at 177-78. Similarly, in this case the plain language of Rules 702 and 703 does not authorize judicial creation of a "general acceptance" requirement.

[7] *See State v. Walters*, 806 P.2d 497, 501 (Mont. 1991) (reaffirming past rejection of the *Frye* test); *State v. Brown*, 687 P.2d 751, 759-60 (Or. 1984) (rejecting *Frye* test as unnecessarily restrictive); *Troutman v. Valley National Bank*, 826 P.2d 810, 815 n.2 (Ariz. Ct. App. 1992) (declining to follow *Frye*).

for the carefully considered substantive law of the States, by engrafting the additional substantive burden of *Frye* onto civil state-law tort litigation.[8] Such abuse of judicial power should be repudiated promptly by this Court.

In the end, Merrell's Opposition demonstrates nothing more than the existence of an argument in favor of the *Frye* rule. Bolstered by this Court's precedents, the plain meaning of the Federal Rules, separation-of-powers doctrine, and this Court's *Erie* jurisprudence, however, petitioners have outlined an opposing and powerful argument in favor of repudiating *Frye*. Taken together, then, the Petition and the Opposition simply demonstrate that the lines of analytic disagreement are clearly drawn and that this case is an excellent vehicle for this Court's review.

3. Certiorari is Warranted on the Peer Review Issue.

Typical of Merrell's overstatements is its claim that petitioners regard peer review as "the functional equivalent of some scholarly inquisition to burn the heretic and reward the devout." Opp. 25.[9] Petitioners argue no such thing. Peer review may be an efficacious

[8] Merrell's citation to *Hanna v. Plumer*, 380 U.S. 460 (1965), is entirely inapposite, as petitioners do not argue the invalidity of a procedural rule promulgated by this Court under the Rules Enabling Act. Instead, petitioners' argument under *Erie* attacks only the Ninth Circuit's use of the judicially created *Frye* and "peer review" tests *in addition to* the statutory standards set forth by Congress and by this Court in duly promulgated rules. Pet. 18-19, 25-26.

[9] Merrell's Opposition is replete with *ad hominem* attacks on the sincerity, professionalism and credibility of petitioners' experts. Merrell has characterized petitioners' experts as "scientific shamans" (Opp. 1), and "credentialed hired guns" (Opp. 14), who engage in "the pursuit of heresy" (Opp. 1), "unscrupulous hucksterism" (Opp. 11), "renegade reanalysis" (Opp. 23), and "pathological science" (Opp. 26) — all "performed at the request of litigants whose undisputed interest lies in finding a causative link." Opp. 25. Incendiary invective is no substitute for concrete analysis. As Judge Becker has noted, "[c]oncerns over 'hucksterism' and false science . . . are nothing new," and they should not affect analysis of whether *Frye* survives the Federal Rules of Evidence, enacted in 1975 — decades after such concerns were first expressed. Becker, *supra*, at 879 & n.117. Merrell's persistent emphasis on adjectives rather than arguments illustrates that it can marshall no legitimate position against a grant of certiorari. Merrell's verbal arsenal should be reserved for trial on the merits.

For the record, the Sixth Circuit, considering some of the same affidavits presented here, found "no suggestion of unethical scientific conduct" on the part of plaintiffs' experts. *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1352 (6th Cir. 1992). And it hardly needs emphasis that *Merrell's* expert witnesses were well compensated and did not testify out of a sense of philanthropy.

method for organizing the publication of academic journals, but it is not a surrogate for the truth-seeking function of civil and criminal justice. *See* Pet. 29-30. More fundamentally, nowhere has Congress delegated control over admissibility of scientific expert testimony to the editors of peer-reviewed journals, even if the peculiarly judicial function of deciding on the admissibility of trial evidence could be delegated to a private entity, *cf. Mistretta v. United States*, 488 U.S. 361, 373 n.7 (1989); *Carter v. Carter Coal Co.*, 298 U.S. 238, 311 (1936); *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 537 (1935), and even if the First Amendment were not implicated by a "forced speech" rule that automatically devalues scientific studies unless they are published for public consumption and thereby penalizes a speaker who chooses to present her work only in the litigation context. *Cf. Planned Parenthood v. Casey*, 112 S. Ct. 2791, 2824 (1992) (joint opinion); *Pacific Gas & Electric Co. v. Public Utility Comm'n of California*, 475 U.S. 1 (1986); *Wooley v. Maynard*, 430 U.S. 705 (1977).[10]

In an argument best directed to Congress, Merrell contends that without the *Frye* rule and peer review, "venal technocrats" will storm the barricades and overwhelm the mental faculties of unwitting jurors. Opp. 23. Apart from the obvious Seventh Amendment problem presented by this argument, *see* Pet. 14, 28-29 n.8, this Court has expressed little patience with such intellectual elitism about the capacities of jurors and of the adversarial system. It is the very "purpose of the jury . . . to sort out the true testimony from the false, the important matters from the unimportant matters, and, when called upon to do so, to give greater credence to one party's expert witnesses than another's. Such matters occur routinely in the American judicial system, both civil and criminal." *Barefoot v. Estelle*, 463 U.S. 880, 902 (1983) (internal quotation omitted).

Indeed, Merrell need not look far to find mechanisms for the "basic screening function to protect the jury from confusing and

[10] Among other things, the fact that peer-reviewed journals are themselves funded by drug companies like Merrell, *see* Pet. 30 n.10, makes it particularly objectionable for control over expert testimony in pharmaceuticals cases to be entrusted to the publication decisions of such journals. Any such delegation, given the "derivative bias" of the journals that must be assumed, *Schweiker v. McClure*, 456 U.S. 188, 196-97 (1982), infringes petitioners' right to "an impartial and disinterested tribunal" for decision of their claims. *Joint Anti-Fascist Committee v. McGrath*, 341 U.S. 123, 172 (1951) (Frankfurter, J., concurring).

misleading evidence." Opp. 14. A variety of tests for scrutinizing expert testimony at the admissibility stage have been authorized by Congress, *none* of which the Ninth Circuit below — in promulgating its *own* test — saw fit even to mention.[11]

CONCLUSION

For all these reasons, certiorari should be granted.

Respectfully submitted,

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August 25, 1992

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[11] Although all relevant expert testimony is presumptively admissible, Fed. R. Evid. 402, courts must ensure that an expert is qualified and is addressing a subject on which expert testimony will be helpful to the jury. Fed. R. Evid. 702. Courts must ensure that, where an expert refers to hearsay information, that information is of the type reasonably relied upon by experts in the particular field in forming opinions on the subject. Fed. R. Evid. 703. Moreover, courts have been granted explicit authority under Fed. R. Evid. 706 to impanel independent experts to aid the jury in the factfinding process. *See, e.g.*, Becker, *supra*, at 884-85; T. Willging, *Court-Appointed Experts* (Fed. Jud. Ctr. 1986).

A court's ability to exclude evidence based on a balancing of probative and prejudicial value under Fed. R. Evid. 403 must also be considered. In his opinion in the *Christophersen* case, Chief Judge Clark emphasized that in assessing a trial court's exclusion of expert testimony it is imperative to consider all potentially applicable evidence rules enacted by Congress, including Rule 403, rather than to create "a homemade test for admissibility" under *Frye*, which ignores "the letter and spirit of the Federal Rules of Evidence." *Christophersen*, 939 F.2d at 1106, 1116, 1120-21 (Clark, C.J., concurring in the result).

Finally, various pretrial discovery and trial disclosure methods are available to strengthen the advocacy system by ensuring efficient and prepared cross-examination of experts at trial. *See, e.g.*, Weinstein, *Improving Expert Testimony*, 20 U. Rich. L. Rev. 473, 483-85 (1986) (discussing selected tools); Pratt, *A Judicial Perspective on Opinion Evidence Under the Federal Rules*, 39 Wash. & Lee L. Rev. 313, 322-25 (1982) (same); Fed. R. Evid. 705 (authorizing trial courts to require prior disclosure of all underlying expert reasoning).

With the wide range of available devices deemed adequate by Congress for supervising expert testimony, it strains credulity to suggest that judges may invent their own devices based on a fear of "venal technocrats." The Ninth Circuit's imposition of additional, unwritten requirements — of "general acceptance" in an arbitrarily defined scientific community, and particularly of publication in a peer-reviewed journal — are inappropriate exercises of judicial power.

Supreme Court, U.S.
FILED
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OFFICE OF THE

No. 92-102

IN THE
Supreme Court of the United States

October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, INDIVIDUALLY AND AS GUARDIANS AD LITEM FOR JASON DAUBERT, AND ANITA DE YOUNG, INDIVIDUALLY AND AS GUARDIAN AD LITEM FOR ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

JOINT APPENDIX

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December 2, 1992

PETITION FOR CERTIORARI FILED JULY 7, 1992
CERTIORARI GRANTED OCTOBER 13, 19092

BATEMAN & SLADE, INC. BOSTON, MASSACHUSETTS

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9-17-84	*Daubert* Answer
12-20-84	*Schuller* Petition for Removal
12-24-84	*Schuller* Answer
2-12-85	*Schuller* transferred to U.S. District Court for the Southern District of Ohio
2-20-85	*Daubert* transferred to U.S. District Court for the Southern District of Ohio
8-16-85	*Daubert* and *Schuller* returned to U.S. District Court for the Southern District of California
8-5-87	Dauberts' Motion to Consolidate *Daubert* and *Schuller* granted as to all phases of liability
10-20-87	Order bifurcating liability and damages issues and barring presence of plaintiff children during trial of the issue of general causation
12-2-88	*Daubert* First Amended Complaint
8-3-89	Defendant's Motion for Summary Judgment on issue of causation
11/1/89	District Court's Memorandum Decision and Order granting summary judgment to Defendant, filed Nov. 1, 1989
12-14-89	*Daubert* and *Schuller* Notices of Appeal (9th Cir. No. 90-55397)
12/20/91	Court of Appeals' decision affirming the District Court, filed Dec. 20, 1991
4/8/92	Court of Appeals' order denying panel rehearing and rehearing en banc, filed Apr. 8, 1992

2. Complaints and answers in *Schuller* and *Daubert* filed May 11, 1984, Sept. 17, 1984, Dec. 24, 1984, and Dec. 2, 1988

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SUPERIOR COURT OF THE STATE OF CALIFORNIA
For the County of San Diego

NO. 521080

MICHAEL SCH[U]LLER, ANITA DE YOUNG, and ANITA DE YOUNG as Guardian ad Litem for ERIC SCH[U]LLER, a Minor,

Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation, (successor to RICHARDSON-MERRELL, INC.), and DOES I through XX, inclusive,

Defendants.

COMPLAINT FOR DAMAGES FOR PERSONAL INJURIES

Come now plaintiffs, MICHAEL SCHULLER, ANITA DE YOUNG, and ERIC SCHULLER, by and through his Guardian ad Litem, ANITA DE YOUNG, and for cause of action against the defendants, and each of them, allege:

FIRST CAUSE OF ACTION

I.

The true names and capacities, whether individual, corporate, associate or otherwise, of defendants, DOES I through XX, inclusive, are unknown to plaintiffs, who therefore sue said defendants by such fictitious names. Plaintiffs are informed and believe and thereon allege that each of the defendants herein designated as a DOE is responsible in some manner for the events and happenings herein referred to and caused injuries and damages proximately thereby as hereinafter alleged.

II.

Defendant MERRELL DOW PHARMACEUTICALS, INC. (hereinafter referred to as "MERRELL"), is a Delaware corporation authorized to do and doing business in the County of San Diego, State of California, to that extent necessary for the jurisdiction of this Court.

III.

Defendants DOES I through V, inclusive, and each of them, were authorized to do and doing business in San Diego, California.

IV.

At all times herein mentioned, defendants, and each of them were engaged in the manufacture, testing, producing, vending, introducing into interstate commerce for sale therein, transporting in interstate commerce for sale therein, advertising, selling and recommending for use to the general public a certain product, to wit, the drug Bendectin.

V.

At all times herein mentioned, each of the defendants herein was the agent, servant and employee of each of the remaining defendants, and at all times mentioned herein each was acting within

the time, place and scope of said agency and employment.

VI.

Defendants, and each of them, knew that if said product was not properly and carefully manufactured, designed, tested, maintained, inspected, and assembled, it would, if used by any member of the general public, be likely to cause serious and permanent injury as is hereinafter more fully set forth.

VII.

Defendants, and each of them, negligently and carelessly designed, manufactured, tested, and sold said product so as to cause it to be in a dangerous and defective and deleterious condition and unsafe for the use and purpose for which it was intended when used as recommended; said condition of said product was known to defendants, and each of them, or should have been discovered by them through the exercise of ordinary care and reasonable diligence, but was not disclosed or made known to plaintiffs and at all times herein mentioned, plaintiffs had no knowledge of said condition or of any danger in the use of said product.

VIII.

The product, Bendectin, was prescribed for ANITA DE YOUNG by her physician during the period when she was pregnant with ERIC SCHULLER; thereafter, as the proximate result of said ingestion during pregnancy, plaintiff ERIC SCHULLER was born on December 18, 1980 with the absence of one hand and other birth defects.

IX.

By reason of the defective, dangerous, deleterious, and unsafe condition of said product, while used in a normal and usual fashion, plaintiff ERIC SCHULLER suffered serious and permanent personal injuries as more fully set forth hereinafter.

X.

As a direct and proximate result of the conduct of the defendants, and each of them, plaintiff ERIC SCHULLER was injured in his health, strength and activity, sustaining severe shock and injuries to his nervous system and person, causing plaintiff

mental, physical and nervous pain and suffering, and resulting in his disability, all to his general damage in a sum which will be shown according to proof.

XI.

As a direct and proximate result of the conduct of the defendants and each of them, plaintiffs were compelled to and did incur expenses for medical care, hospitalization, and other incidental expenses and will have to incur additional like expenses in the future, all in amounts presently unknown to them. Plaintiffs therefore ask leave of court either to amend this complaint so as to show the amount of medical expenses, when ascertained, or to prove said amount at the time of trial.

XII.

As a direct and proximate result of the conduct of the defendants, and each of them, plaintiff ERIC SCHULLER was disabled and will be disabled in the future. Plaintiff has therefore lost earnings and may continue to lose earnings in the future, all in amounts presently unknown to him. Plaintiff asks leave of court either to show the amount of his lost earnings, when ascertained, or to prove said amount at the time of trial.

SECOND CAUSE OF ACTION

I.

Plaintiffs hereby incorporate herein each and every allegation contained in plaintiffs' First Cause of Action on file herein as though fully set fort in length.

II.

Defendants, and each of them, were engaged in the manufacture, testing, producing, introducing into interstate commerce for sale therein, transporting in interstate commerce for sale therein, delivering, advertising, selling, assembling, and recommending to the general public the drug Bendectin for use in the County of San Diego, with all knowledge that said product was to be used by the general public; and that defendants, and each of them, represented and warranted said product was fit for the purposes intended.

III.

During the period that plaintiff ANITA DE YOUNG was pregnant with plaintiff ERIC SCHULLER, she relied upon said representations and warranties and had no knowledge of the unsafe quality of said product.

IV.

Said product was not fit for the purpose for which it was intended in that it was so defectively designed, manufactured, tested, produced, delivered and sold that when used by plaintiff ANITA DE YOUNG in the usual and normal manner, it caused the serious and personal injuries to plaintiff ERIC SCHULLER more fully set forth hereinabove.

THIRD CAUSE OF ACTION

I.

Plaintiffs hereby incorporate herein each and every allegation contained in the First and Second Causes of Action on file herein as though set forth at length.

II.

Defendants, and each of them, warranted and represented that said product was of merchantable quality.

III.

Said product was not of merchantable quality in that when used in a normal manner by plaintiff ANTIC DE YOUNG, it caused the serious and permanent personal injuries to plaintiff ERIC SCHULLER more fully set forth hereinabove.

FOURTH CAUSE OF ACTION

I.

Plaintiffs hereby incorporate herein each and every allegation contained in first three Causes of Action on file herein as though fully set forth at length.

II.

Defendants, and each of them, expressly and by advertising, warranted and represented to the general public and to plaintiffs that

said product was reasonably fit for the purpose for which it was intended.

III.

Plaintiffs relied on said warranties and representations.

IV.

Said product was not fit for the purpose for which it was intended and that, when used in a normal and usual manner, it caused the serious personal injuries more fully set forth hereinabove.

FIFTH CAUSE OF ACTION

I.

Plaintiffs hereby incorporate herein each and every allegation contained in the first four Causes of Action on file herein as though fully set forth at length.

II.

Defendants, and each of them, introduced into the stream of commerce in the United States that certain product more fully described hereinabove while it was in a dangerous and defective condition.

III.

As a direct and proximate result of the dangerous and defective condition of the drug Bendectin, plaintiff ERIC SCHULLER was born with the absence of one hand and other birth defects.

IV.

Defendants, and each of them, are strictly liable to plaintiffs because of the dangerous and defective nature of said product.

SIXTH CAUSE OF ACTION

I.

Plaintiffs hereby incorporate herein each and every allegation contained in the first five Causes of Action on file herein as though fully set forth at length.

II.

Said product, the drug Bendectin, was in a dangerous and defective condition when introduced into the stream of commerce by the defendants, and each of them, in that when used in a normal fashion, it could and would cause serious personal injuries to the users thereof.

III.

The above facts were known to the defendants, and each of them, or in the exercise of due care should have been known to the defendants, and each of them, and in this condition, defendants possessed special knowledge of the materials, design and character of said product. At no time did plaintiffs possess any special knowledge and at no time were they aware that said product was dangerous and defective as aforesaid.

IV.

Although possessed of special knowledge of the dangerous and defective condition and the dangerous propensities of said product, defendants, and each of them, negligently and carelessly failed to warn the plaintiffs of the dangerous and defective condition of said product.

WHEREFORE, plaintiffs pray judgment against the defendants, and each of them, as follows:

For the First, Second, Third, Fourth, Fifth and Sixth Causes of Action:

1. For general damages as proven at the time of trial;
2. For special damages as proven at the time of trial;
3. For lost wages;
4. For costs of suit; and
5. For such other and further relief as the Court may deem proper.

DATED: May 11, 1984 CASEY, GERRY, CASEY, WESTBROOK, REED & HUGHES
By: /s/
FREDERICK SCHENK
Attorneys for Plaintiffs

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Attorneys for Defendant,
MERRELL DOW PHARMACEUTICALS INC.

UNITED STATES DISTRICT COURT
For the Southern District of California

NO. 84-2929-K(M)

MICHAEL SCH[U]LLER, ANITA DE YOUNG, and ANITA DE YOUNG as Guardian ad Litem for ERIC SCH[U]LLER, a Minor,

Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation, (successor to RICHARDSON-MERRELL, INC.), and DOES I through XX, inclusive,

Defendants.

COMPLAINT FOR DAMAGES

ANSWER OF DEFENDANT MERRELL DOW PHARMACEUTICALS INC. TO COMPLAINT

Defendant Merrell Dow Pharmaceuticals Inc., a corporation, answers the complaint for damages for personal injuries, and admits, denies and alleges as follows:

FIRST DEFENSE
(FIRST CAUSE OF ACTION)

1. Defendant Merrell Dow Pharmaceuticals Inc. (hereinafter Merrell Dow) states that it is without knowledge

or information sufficient to form a belief as to the truth of the allegations contained in Paragraph I.

2. Defendant denies each and every allegation contained in paragraph II, except to admit that defendant Merrell Dow is a corporation doing business in the State of California.

3. Defendant states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph III.

4. Defendant denies each and every allegation contained in paragraph IV, except to admit that defendant manufactured, distributed and marketed the pharmaceutical product, Bendectin.

5. Defendant denies each and every allegation contained in paragraph V.

6. Defendant denies each and every allegation continued in paragraph VI.

7. Defendant denies each and every allegation contained in paragraph VII.

8. Defendant denies each and every allegation contained in paragraph VIII, except to state that it is without knowledge or information sufficient to form a belief as to the truth of the allegation that Bendectin was prescribed for plaintiff-mother by her physician during her pregnancy with plaintiff Eric Schuller.

9. Defendant denies each and every allegation contained in paragraph IX.

10. Defendant denies each and every allegation contained in paragraph X.

11. Defendant denies each and every allegation contained in paragraph XI.

12. Defendant denies each and every allegation contained in paragraph XII.

SECOND DEFENSE
(SECOND CAUSE OF ACTION)

13. Defendant Merrell Dow incorporates herein its responses to the First Cause of Action hereinabove as though set forth in full.

14. Defendant denies each and every allegation contained in paragraph II, except to admit that defendant manufactured,

distributed and marketed the pharmaceutical product, Bendectin.

15. Defendant denies each and every allegation contained in paragraph III, except to state that it is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning what plaintiff-mother relied upon and her knowledge concerning Bendectin.

16. Defendant denies each and every allegation contained in paragraph IV.

THIRD DEFENSE
(THIRD CAUSE OF ACTION)

17. Defendant Merrell Dow incorporates herein its responses to the First and Second Causes of Action hereinabove as though set forth in full.

18. Defendant denies each and every allegation contained in paragraph II.

19. Defendant denies each and every allegation contained in paragraph III.

FOURTH DEFENSE
(FOURTH CAUSE OF ACTION)

20. Defendant Merrell Dow incorporates herein its responses to the first three Causes of Action hereinabove as though set forth in full.

21. Defendant denies each and every allegation contained in paragraph II.

22. Defendant denies each and every allegation contained in paragraph III, except to state that it is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning what plaintiffs relied upon.

23. Defendant denies each and every allegation contained in paragraph IV.

FIFTH DEFENSE
(FIFTH CAUSE OF ACTION)

24. Defendant Merrell Dow incorporates herein its responses to the first four Causes of Action hereinabove as though set forth in full.

25. Defendant denies each and every allegation contained in paragraph II.

26. Defendant denies each and every allegation contained in paragraph III.

27. Defendant denies each and every allegation contained in paragraph IV.

SIXTH DEFENSE
(SIXTH CAUSE OF ACTION)

28. Defendant Merrell Dow incorporates herein its responses to the first five Causes of Action hereinabove as though set forth in full.

29. Defendant denies each and every allegation contained in paragraph II.

30. Defendant denies each and every allegation contained in paragraph III, except to state that it is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning plaintiff's knowledge.

31. Defendant denies each and every allegation contained in paragraph IV.

FIRST AFFIRMATIVE DEFENSE

1. Plaintiffs' complaint and each claim contained therein fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

2. Plaintiffs' complaint and each claim contained therein is barred by the provisions of the applicable statutes of limitations.

THIRD AFFIRMATIVE DEFENSE

3. Alleges that the plaintiff-mother was fully informed of the risks, if any, involved in the taking of the pharmaceutical product set forth in plaintiffs' complaint and that the plaintiff-mother voluntarily consented thereto, thereby assuming all of the said risks, and thereby becoming the sole proximate cause of any injury, damage or loss to the plaintiffs.

FOURTH AFFIRMATIVE DEFENSE

4. Alleges that if the plaintiffs were injured in any way as a result of any act or omission of defendant, that such was caused and contributed to by their own negligence under the circumstances then existing, and the disabilities, if any which they suffered were likewise so caused and contributed to by their failure to follow the advice and direction of their physicians, nurses and other health care providers and their unreasonable refusal to have medical care and attention and their failure to use ordinary care.

FIFTH AFFIRMATIVE DEFENSE

5. Alleges that if the plaintiffs were injured in any way as a result of any act or omission of the defendant, then such was caused and contributed to by the plaintiff-mother's carelessness, negligence and willfulness under the circumstances then existing and the disabilities, if any, which the plaintiffs suffered, were likewise so caused and contributed to by plaintiff-mother's failure to follow the advice, instructions and directions of her physicians, nurses and other health care providers and her unreasonable refusal to have medical care and attention and by plaintiff-mother's failure to use ordinary care.

SIXTH AFFIRMATIVE DEFENSE

6. Alleges that if it is found that this defendant was negligent or otherwise at fault, which this answering defendant denies, then the conduct, negligence or fault of the plaintiffs or other parties to this action and other persons or entities unknown, must be compared to determine a degree of fault, if any, among said parties and the damages sustained by the plaintiffs, if any, must be reduced and apportioned in relationship to the degree of fault, if any, among the parties.

SEVENTH AFFIRMATIVE DEFENSE

7. Alleges that the injuries in question and damages in question, if any, were the result of the misuse of the product in question. Defendant further alleges that if plaintiffs suffered injuries attributable to the use of any pharmaceutical product

manufactured by this defendant, which allegations are expressly denied, then the injuries, if any, were solely caused and attributable to the unreasonable, unforeseeable and improper use of said pharmaceutical product by plaintiff-mother.

EIGHT AFFIRMATIVE DEFENSE

8. Alleges that the product in question was used after knowledge of the defect, if any, that existed therein.

NINTH AFFIRMATIVE DEFENSE

9. Alleges that any injury, damage or loss allegedly suffered by the plaintiffs was proximately caused by plaintiff-mother's failure to use reasonable means to prevent aggravation of the plaintiff's condition and plaintiff-mother's failure to use reasonable means to mitigate damages, if any, to the plaintiffs.

TENTH AFFIRMATIVE DEFENSE

10. Alleges that the conduct of the plaintiffs, or the conduct of other entities and individuals other than this defendant, whether or not parties herein, proximately caused or contributed to the plaintiffs' alleged injuries and damages. Said conduct comparatively caused or contributed to plaintiffs' alleged injuries and damages. Should it be found that this answering defendant is negligent, which this answering defendant expressly denies, said conduct should comparatively reduce the percentage of any negligence attributable to this defendant.

ELEVENTH AFFIRMATIVE DEFENSE

11. Alleges that all claims are barred in whole or in part by the provisions of the California Commercial Code, section 2725.

TWELFTH AFFIRMATIVE DEFENSE

12. Alleges that plaintiffs' claims are barred by reason of the doctrine of laches and by the fundamental unfairness and prejudice of the excessive and lengthy delay from the date of the alleged ingestion of the pharmaceutical product to the filing of the complaint.

THIRTEENTH AFFIRMATIVE DEFENSE

13. Alleges that the complaint and each claim therein, is barred in that the plaintiffs lack standing to sue this defendant on the claims alleged therein.

FOURTEENTH AFFIRMATIVE DEFENSE

14. Alleges that the manufacture, distribution and sale of the pharmaceutical product referred to in plaintiffs' complaint was at all times in compliance with the Federal Food, Drug and Cosmetic Act.

FIFTEENTH AFFIRMATIVE DEFENSE

15. Alleges that no action or omission of this defendant was a substantial factor in bringing about the alleged injuries of the plaintiffs, nor was any act or omission a contributing cause thereof and any alleged acts or omissions of this defendant were superseded by the acts or omissions of others, including plaintiffs, which were the independent, intervening and proximate cause of any injury, damages or loss sustained by the plaintiffs.

SIXTEENTH AFFIRMATIVE DEFENSE

16. Alleges that, at or about the time, date and place mentioned in the complaint that if any risk was attendant upon plaintiffs' activities which defendant denies, the plaintiffs full well knew of such risks, and voluntarily, and without compulsion or coercion, encountered such risks.

SEVENTEENTH AFFIRMATIVE DEFENSE

17. Alleges that all claims are barred in whole or in part by the applicable statute of limitations (California Code of Civil Procedure, section 340(3).)

EIGHTEENTH AFFIRMATIVE DEFENSE

18. Alleges that all claims are barred in whole or in part by the applicable statute of limitations (California Code of Civil Procedure, section 340.5.)

NINETEENTH AFFIRMATIVE DEFENSE

19. Alleges that all claims are barred in whole or in part by the applicable statute of limitations (California Code of Civil Procedure, section 339(1).)

TWENTIETH AFFIRMATIVE DEFENSE

20. Alleges that all claims are barred in whole or in part by the applicable statute of limitations (California Code of Civil Procedure, section 337(1).)

TWENTY-FIRST AFFIRMATIVE DEFENSE

21. Alleges that all claims are barred in whole or in part by the applicable statute of limitations (California Code of Civil Procedure, section 338(1).)

WHEREFORE, this defendant prays that plaintiffs take nothing by their claims, for defendant's costs of suit, and for such other and further relief as the court deems proper.

DATED: December 21, 1984. HAIGHT, DICKSON, BROWN & BONESTEEL
JEFFERY J. CARLSON
JOSEPH R. ZAMORA

By: /s/
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Attorneys for Plaintiffs WILLIAM and JOYCE DAUBERT, Individually, and As Guardians Ad Litem for JASON DAUBERT

UNITED STATES DISTRICT COURT
For the Southern District of California

NO. 84-2013-G(I)

WILLIAM DAUBERT; JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT, a minor,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50 inclusive,
Defendants.

FIRST AMENDED COMPLAINT FOR DAMAGES (NEGLIGENCE, STRICT LIABILITY AND BREACH OF WARRANTY)

NO. 84-2929-G(I)

MICHAEL SCHULLER, ANITA DE YOUNG, and ANITA DE YOUNG as Guardian Ad Litem for ERIC SCHULLER,

Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES I through XX., inclusive

Defendants.

FIRST CAUSE OF ACTION
(Strict Liability)

1. At the time of the events complained of herein, plaintiffs William Daubert and Joyce Daubert were residents of the City of Chagrin Falls, State of Ohio. They are the natural parents of Jason Daubert and have been appointed Guardians Ad Litem for purposes of this litigation by order of this Court.

2. Plaintiff Jason Daubert is a minor and was born in and is a resident of the County of San Diego, California.

3. Plaintiffs are informed and believe that defendant Merrell Dow Pharmaceuticals, Inc., is an Ohio corporation, licensed to do business and doing business in the State of California. Defendant Merrell Dow Pharmaceuticals, Inc. (hereinafter "Merrell Dow") was at all times herein mentioned engaged in the business of designing, testing, studying, developing, manufacturing, producing, advertising, selling and distributing drugs and pharmaceutical products, and specifically a drug named Bendectin for sale to and use by members of the general public.

4. The true names and capacities of defendants named herein as DOES 1 through 50, inclusive, are unknown to plaintiffs, who therefore sue said defendants, and each of them, by such fictitious names. Plaintiffs will amend this Complaint to show the true names and capacities when they have been ascertained. Plaintiffs are informed and believe, and thereon allege, that each of the said fictitiously named defendants is responsible in some manner for the

occurrences hereinafter alleged, and that plaintiffs' injuries as herein alleged were proximately caused by said actions.

5. Defendant intended that the drug Bendectin, which was designed, developed, produced, sold and distributed by them, be advertised, sold and/or distributed without warnings as a safe method of controlling nausea and illness during pregnancy.

6. At all times herein mentioned, the defendant knew and intended that Bendectin would be distributed to, purchased by and consumed by members of the general public without inspection for defects and without testing.

7. In or about December 1972 and January of 1983, plaintiff Joyce Daubert was prescribed the drug Bendectin by her physician. She purchased and consumed the drug in accordance with the physician's instructions.

8. Jason Daubert was born on July 26, 1973 with serious and disabling birth deformities and abnormalities. The plaintiffs were not aware that Bendectin was the cause of those abnormalities and deformities until, in late August or early September of 1983, after reading of a June, 1983 jury verdict finding that the product caused birth defects of the same kind suffered by Jason, and after reading in June of 1983 that the product was removed from the market, Joyce Daubert obtained the medical records of the physician who had treated her during her pregnancy and learned that she had been given Bendectin.

9. At the time that she purchased and consumed Bendectin, it was defective and unsafe for its intended purpose in that it failed to warn of the possibility of deformation of the child being carried during the pregnancy, and it was defective in that it caused deformations in children whose mothers consumed the drug during pregnancy.

10. As a proximate result of the conduct of the defendant, plaintiff Jason Daubert was born with permanent deformities and abnormalities. Those deformities and abnormalities have caused Jason and his family, including his mother Joyce, and father William, who observed his birth in the deformed condition, severe emotional distress, all to their general damage.

11. As a further proximate result of the conduct of the defendant, plaintiffs William and Joyce Daubert have incurred, and will continue to incur, medical and related expenses, all to their

special damage. Plaintiff Jason Daubert will incur medical expenses for the remainder of his natural life, all to his special damage according to proof at the time of trial.

12. As a further result of the conduct of the defendants, plaintiff Jason Daubert has suffered great mental and physical pain and suffering and permanent disability, all to his general damage according to proof at the time of trial.

13. As a further proximate result of the conduct of the defendant, plaintiff Jason Daubert has suffered loss of occupational choices and a loss of future earning capacity, all to his general and special damage according to proof at the time of trial.

14. As a further result of the conduct of the defendant, plaintiffs William Daubert and Joyce Daubert were prevented from attending to and will be prevented in the future from attending to their usual occupations while caring for, treating, and arranging for the treatment of plaintiff Jason Daubert, thereby losing past and future earnings, all to their special damage in an amount according to proof at the time of trial.

15. Plaintiffs are informed and believe and upon such information and belief allege that defendant failed to properly design, develop, prepare, produce, test, manufacture and market Bendectin maliciously and in conscious disregard of the safety of the consuming public. Defendant had notice of the relationship between Bendectin and birth defects as early as 1962. Over the next 20 years defendant received reports from independent researchers, the FDA, and their own research staff linking Bendectin to birth defects; specifically limb-reduction defects like that suffered by Jason Daubert. In November, 1962 defendant received a report from the FDA linking Bendectin and limb-reduction defects. Defendant's teratological studies conducted in 1963 confirmed a significant relationship between Bendectin and birth defects and acknowledged the need for more research; defendant failed to conduct any additional animal studies. By 1972, defendant received notice of ninety-six (96) cases of congenital malformations occurring in association with Bendectin usage.

Knowing of the link between Bendectin and birth defects, defendant failed to take the necessary steps to properly prepare, test and market their product. Defendant conducted unscientific and biased studies that misrepresented the safety of Bendectin to the

medical profession and the public. Defendant also withheld information from the FDA that supported the relationship between Bendectin and birth defects.

In addition, defendant marketed, advertised and sold Bendectin without warnings in conscious disregard of the safety of the consuming public and the children whose mothers would ingest the drug during pregnancy. Defendant had notice of the dangerous nature of their drug. Defendant failed to warn of the known or reasonably knowable side effects associated with Bendectin. The relationship between Bendectin and birth defects was willfully, wrongfully and maliciously withheld from the medical profession and the public in conscious disregard of the safety of those who used Bendectin.

Plaintiffs seek punitive or exemplary damages as a result of defendant's conduct, in an amount sufficient to punish or set an example of defendant.

SECOND CAUSE OF ACTION
(Breach of Warranty)

1. Plaintiffs incorporate herein by reference paragraphs 1 through 8 and 10 through 15, inclusive, of the First Cause of Action as though set forth in full herein.

2. Defendant impliedly warranted to Joyce Daubert, as an intended user, that Bendectin would be fit for its intended purpose without warnings as to the potential dangerous consequences of consumption of the drug. Defendant breached that implied warranty by failing to make the drug safe and by failing to warn of the dangerous potentials of its consumption.

THIRD CAUSE OF ACTION
(Negligence)

1. Plaintiffs incorporate herein by reference paragraphs 1 through 8 and 10 through 15, inclusive, of the First Cause of Action as though set forth in full herein.

2. Defendant had a duty to thoroughly research, test and examine the drug which it manufactured before manufacturing it, and had a duty to safely design, develop, prepare, produce, manufacture, and distribute the drug it made, and defendant had a duty to adequately warn of the dangers associated with consuming

the drug, before or at the time of marketing the drug.

3. Defendant breached all of the aforesaid duties by failing to thoroughly research and examine the drug it manufactured before manufacturing it, and by failing to safely design, develop, produce, manufacture and distribute the drug it made, and by failing to warn of the possible dangerous consequences of ingestion of the drug.

WHEREFORE, plaintiffs pray for judgment against defendant as follows:

1. For general damages according to proof;
2. For medical and related and incidental expenses according to proof;
3. For loss of earnings and earning capacity according to proof;
4. For punitive damages in an amount sufficient to punish or set an example of defendant for its failure to properly prepare and market Bendectin, and its failure to warn the medical profession or consuming public of the known or reasonably knowable side effects associated with the drug, in conscious disregard of the safety of the children whose mothers used Bendectin;
5. For cost of suit;
6. For pre-judgment interest; and
7. For such other and further relief as the Court may deem just and proper.

LUCE, FORWARD, HAMILTON & SCRIPPS

By:_____/s/_____
Mary F. Gillick, Attorneys for Plaintiffs WILLIAM and JOYCE DAUBERT, Individually, and as Guardian Ad Litem for JASON DAUBERT

[Declaration of service omitted]

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Attorneys for Defendant,
MERRELL DOW PHARMACEUTICALS INC.

UNITED STATES DISTRICT COURT
For the Southern District of California

NO. 84-2013-G(I)

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians ad Litem for JASON DAUBERT and JESSICA DAUBERT, minors,

Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., DOW CHEMICAL COMPANY and DOES 1 through 50 inclusive,

Defendants.

ANSWER OF DEFENDANT MERRELL DOW PHARMACEUTICALS INC. TO COMPLAINT; DEMAND FOR JURY TRIAL

Defendant Merrell Dow Pharmaceuticals Inc. ("Merrell Dow"), answers the plaintiffs' unverified complaint (hereinafter "complaint") as follows:

FIRST DEFENSE
(FIRST CAUSE OF ACTION)

1. Defendant Merrell Dow is without sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 1.

2. Defendant Merrell Dow is without sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 2.

3. Defendant Merrell Dow denies each and every allegation of paragraph 3 except to admit that it has its principal place of business in the state of Ohio, that it is licensed to do business and is doing business in the state of California, and that it was engaged in the manufacture and distribution of the prescription product Bendectin.

4. Defendant Merrell Dow is without sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 4.

5. Defendant Merrell Dow denies each and every allegation of paragraph 5, except to admit that it was engaged in the production and distribution of Bendectin which was sold as a prescription drug for the purposes of treating nausea during pregnancy.

6. Defendant Merrell Dow denies each and every allegation of paragraph 6.

7. Defendant Merrell Dow is without sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 7.

8. Defendant Merrell Dow denies that Bendectin was the cause of any birth defects allegedly suffered. As to the other allegations of this paragraph, defendant Merrell Dow is without sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 8.

9. Defendant Merrell Dow denies each and every allegation of paragraph 9.

10. Defendant Merrell Dow denies each and every allegation of paragraph 10.

11. Defendant Merrell Dow denies each and every allegation of paragraph 11.

12. Defendant Merrell Dow denies each and every allegation of paragraph 12.

13. Defendant Merrell Dow denies each and every allegation of paragraph 13.

14. Defendant Merrell Dow denies each and every allegation of paragraph 14.

15. Defendant Merrell Dow denies each and every allegation of paragraph 15.

SECOND DEFENSE
(SECOND CAUSE OF ACTION)

1. Defendant Merrell Dow incorporates by reference its prior responses to the allegations, contained in paragraphs 1-15 of the first defense above as though fully set forth herein.

2. Defendant Merrell Dow denies each and every allegation of paragraph 2.

THIRD DEFENSE
(THIRD CAUSE OF ACTION)

1. Defendant Merrell Dow incorporates by reference its prior responses to the allegations of the complaint, contained in paragraphs 1-15 of the first defense above, and 1 and 2 of the second defense as though fully set forth herein.

2. Defendant Merrell Dow denies each and every allegation of paragraph 2 except to state that Defendant Merrell Dow met all of its legal duties.

3. Defendant Merrell Dow denies each and every allegation of paragraph 3.

FIRST SEPARATE AND AFFIRMATIVE DEFENSE

1. At or about the time, date and place mentioned in the Complaint that if any risk was attendant upon Plaintiffs' activities, which Defendant denies, the Plaintiffs full well knew of such risks, and voluntarily, and without compulsion or coercion encountered such risk.

SECOND SEPARATE AND AFFIRMATIVE DEFENSE

2. The Plaintiff-mother and Plaintiff-father were fully informed of the risk, if any, involved in taking of the

pharmaceutical product set forth in Plaintiffs' Complaint and the Plaintiff-mother and Plaintiff-father voluntarily consented thereto, thereby assuming all of said risk, and thereby becoming the sole proximate cause of any injury, damage or loss to the Plaintiffs.

THIRD SEPARATE AND AFFIRMATIVE DEFENSE

3. If the Plaintiffs were injured in any way as a result of any act or omission of Defendant, then such was caused and contributed to by their own negligence under the circumstances then existing, and the disabilities, if any, which they suffered were likewise so caused and contributed to by their failure to follow the advice and direction of their physicians, nurses and other health care providers and their unreasonable refusal to have medical care and attention and their failure to use ordinary care.

FOURTH SEPARATE AND AFFIRMATIVE DEFENSE

4. If the Plaintiffs were injured in any way as a result of any act or omission of Defendant, then such was caused and contributed to by Plaintiffs' carelessness, negligence and willfulness under the circumstances then existing and the disabilities, if any, which the Plaintiffs suffered, were likewise so caused and contributed to by Plaintiffs' failure to follow the advice, instructions and directions of their physicians, nurses and other health care providers and their unreasonable refusal to have medical care and attention and by Plaintiffs' failure to use ordinary care.

FIFTH SEPARATE AND AFFIRMATIVE DEFENSE

5. If it is found that this Defendant was negligent or otherwise at fault, which this answering Defendant denies, then the conduct, negligence or fault of the Plaintiffs, other parties to this Action and other persons or entities unknown, must be compared to determine the degree of fault, if any, among said parties, and the damages sustained by the Plaintiffs must be reduced and apportioned in relationship to the degree of fault, if any, among the parties, and other person and entities unknown.

SIXTH SEPARATE AND AFFIRMATIVE DEFENSE

6. The injuries in question and damages in question were the result of the misuse of the product in question. Defendant further

alleges that if Plaintiffs suffered injuries attributable to the use of any pharmaceutical product distributed by this Defendant, which allegations are expressly denied, then the injuries, if any, were solely caused and attributable to the unreasonable, unforeseeable and improper use of said pharmaceutical product by Plaintiffs.

SEVENTH SEPARATE AND AFFIRMATIVE DEFENSE

7. The product in question was used after knowledge of the defect, if any, that existed therein.

EIGHTH SEPARATE AND AFFIRMATIVE DEFENSE

8. Any injury, damage or loss allegedly suffered by the Plaintiffs, is proximately caused by Plaintiffs' failure to use reasonable means to prevent aggravation of the Plaintiffs' condition and Plaintiffs' failure to use reasonable means to mitigate damage, if any, to the Plaintiffs.

NINTH SEPARATE AND AFFIRMATIVE DEFENSE

9. All claims are barred in whole or in part by the applicable Statute of Limitations Code of Civil Procedure section 340(3).

TENTH SEPARATE AND AFFIRMATIVE DEFENSE

10. All claims are barred in whole or in part by the applicable Statute of Limitations Code of Civil Procedure section 340.5.]

ELEVENTH SEPARATE AND AFFIRMATIVE DEFENSE

11. All claims are barred in whole or in part by the applicable Statute of Limitations Code of Civil Procedure section 339(1).]

TWELFTH SEPARATE AND AFFIRMATIVE DEFENSE

12. All claims are barred in whole or in part by the applicable Statute of Limitations Code of Civil Procedure section 337(1).]

THIRTEENTH SEPARATE AND AFFIRMATIVE DEFENSE

13. All claims are barred in whole or in part by the applicable Statute of Limitations Code of Civil Procedure section 338(4).]

FOURTEENTH SEPARATE AND AFFIRMATIVE DEFENSE

14. The Complaint is barred by the provisions of Civil Code section 29 in that at the time of the alleged injury, if any, the minor Plaintiff was beginning to develop in the nascent state and the alleged injury occurred prior to or in the course of her birth.

FIFTEENTH SEPARATE AND AFFIRMATIVE DEFENSE

15. All claims are barred in whole or in part by the provisions of California Commercial Code section 2725.

SIXTEENTH SEPARATE AND AFFIRMATIVE DEFENSE

16. The Complaint is barred by reason by the Doctrine of Laches and by the fundamental unfairness and prejudice of the excessive and lengthy delay from the date of the alleged ingestion of the pharmaceutical product to the filing of the Complaint.

SEVENTEENTH SEPARATE AND AFFIRMATIVE DEFENSE

17. The Complaint, and each Cause of Action therein, is barred in that the Plaintiffs lack standing to sue this Defendant on the claims alleged in the Complaint.

EIGHTEENTH SEPARATE AND AFFIRMATIVE DEFENSE

18. The Complaint and each Cause of Action therein, is barred by the provisions of the Code of Civil Procedure, section 389 in that Plaintiffs have failed to join as a party to this action, a party or parties in whose absence complete relief cannot be afforded to the Plaintiffs, to which this Defendant denies the Plaintiffs are entitled.

NINETEENTH SEPARATE AND AFFIRMATIVE DEFENSE

19. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were in all times in compliance with the Federal Food, Drug and Cosmetic Act.

TWENTIETH SEPARATE AND AFFIRMATIVE DEFENSE

20. Plaintiffs' Complaint, and each purported cause of action set forth therein, is barred by the Doctrine of En Ventre Sa Mere in that the alleged injury occurred prior to the minor Plaintiff's birth while the minor Plaintiff was in utero.

TWENTY-FIRST SEPARATE AND AFFIRMATIVE DEFENSE

21. No action or omission of this Defendant was a substantial factor in bringing about the alleged injuries of the Plaintiffs, nor was any act or omission a contributing cause thereof and any alleged acts or omissions of this Defendant were superseded by the acts or omissions of others, including Plaintiffs, which were the independent, intervening and proximate cause of any injury, damage, or loss sustained by Plaintiffs.

TWENTY-SECOND SEPARATE AND AFFIRMATIVE DEFENSE

22. The Complaint and each Cause of Action contained therein does not state facts sufficient to constitute a cause of action against this answering Defendant.

TWENTY-THIRD SEPARATE AND AFFIRMATIVE DEFENSE

23. The Complaint does not state facts sufficient to constitute a claim for punitive damages.

WHEREFORE, Defendant prays for judgment herein, for Defendant's costs of suit incurred, and for such other and further relief as the court may deem just and proper.

DATED: September 13, 1984

HAIGHT, DICKSON, BROWN & BONESTEEL
JEFFERY J. CARLSON
JOSEPH R. ZAMORA
JOSEPH L. GATTUSO

By: /s/
JOSEPH L. GATTUSO
Attorneys for Defendant
MERRELL DOW PHARMACEUTICALS INC.

DEMAND FOR JURY TRIAL

Defendant Merrell Dow Pharmaceuticals Inc. demands a trial of the above entitled matter by jury, pursuant to Federal Rules of Civil Procedure, section 38.(b).

DATED: September 13, 1984

HAIGHT, DICKSON, BROWN & BONESTEEL
JEFFERY J. CARLSON
JOSEPH R. ZAMORA
JOSEPH L. GATTUSO

By: /s
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Attorneys for Defendant
MERRELL DOW PHARMACEUTICALS INC.

3. Statement of Steven H. Lamm, M.D., D.T.P.H., and curriculum vitae (Ex. A to Deft.'s Mot. for Summ. Judg.), filed Aug. 3, 1989, and excerpts of deposition in *Will v. Richardson-Merrell, Inc.* (Ex. 23 to Pltfs.' Opp. to Summ. Judg.), filed Aug. 22, 1989

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Attorneys for Plaintiffs WILLIAM and JOYCE DAUBERT, Individually, and As Guardians Ad Litem for JASON DAUBERT

UNITED STATES DISTRICT COURT
For the Southern District of California

NO. 84-2013-G(I)

WILLIAM DAUBERT; JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT, a minor,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50 inclusive,
Defendants.

NO. 84-2929-G(I)

MICHAEL SCHULLER, ANITA DE YOUNG, and ANITA DE YOUNG as Guardian Ad Litem for ERIC SCHULLER,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES I through XX., inclusive

Defendants.

STATEMENT OF STEVEN H. LAMM, M.D., DTPH

I am a physician and epidemiologist who specializes in assessing the magnitude of risk from exposures to various chemical and biological substances. I am currently the president of Consultants in Epidemiology and Occupational Health, Inc. at 2428 Wisconsin Avenue, N.W., Washington, D.C. 20007. In this capacity, I evaluate the risks of various cancers and birth defects from specific exposures. I have attached hereto my curriculum vitae, which includes a bibliography of various medical articles that I have authored or co-authored.

I first became involved in the Bendectin litigation when asked by the Guardian ad litem for class B plaintiffs, Samuel H. Porter, esq. in the multidistrict litigation in Cincinnati, In Re Richardson-Merrell, Inc. "Bendectin" Product Liability Litigation II, MDL No. 486, to prepare a report for Judge Carl Rubin who had certified a class action in that litigation.

I was sought by the Guardian ad litem to prepare a report for Judge Rubin to assist him in identifying the characteristics of the class. Preparation of this report necessitated assessment of the magnitude of risk of birth defects from maternal ingestion of Bendectin. In order to do this, I reviewed the literature submitted to the court by plaintiffs' and defendant's experts. In the preparation of my preliminary report (October 15, 1984), I reviewed the world's literature on Bendectin and human birth defects, including

all those articles relied upon by either the experts for the plaintiffs or the defendants. These studies included reports on over 130,000 newborn infants. In toto, they showed no difference in the risk of birth defects between those infants whose mothers had taken Bendectin during the first trimester of pregnancy and those infants whose mothers had not.

I next reviewed in a similar manner the literature on Bendectin and limb reduction birth defects. I found no association between Bendectin and the occurrence of limb reduction birth defects.

In addition to reviewing the published scientific literature, I reviewed the overall experience that American women concurrently had with birth defects and with Bendectin usage during the years 1976 to 1984. I found no relationship between the annual frequency of Bendectin usage and the annual occurrences of specific birth defects. As no birth defects showed a drop in frequency when there was a drop in the frequency of Bendectin use, I concluded that there was no evidence from this data that Bendectin usage had anything to do with birth defect rates.

Since the time of that report, I have continued to monitor the literature and data on birth defect rates and on Bendectin usage. My current conclusions are no different from my conclusion of 1984, which is that although approximately 3-4% of all human births exhibit some congenital malformations, the frequency is no greater for the infants of mothers who took Bendectin during the first trimester of pregnancy than for the infants of mothers who did not take Bendectin during the first trimester of pregnancy. Based on my review of the scientific literature, I conclude that maternal use of Bendectin during the first trimester of pregnancy is not a risk factor for human birth defects in general, for limb reduction defects specifically, or for any other particular human birth defect.

I declare under penalty of perjury that the foregoing is true and correct.

/s/
STEVEN H. LAMM, M.D., DTPH

Washington, D.C.

Subscribed and sworn to before me
this 1 day of August 1989.
[notarization omitted]

CURRICULUM VITAE

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Consultants in Epidemiology and Occupational Health, Inc.
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Education:

1973-1974 London School of Hygiene and Tropical Medicine
London, England
Diploma in Tropical Public Health (DTPH)

1972-1973 Albert Einstein College of Medicine
New York, New York
Residency-Pediatrics

1969-1970 Montreal Children's Hospital
Montreal, Quebec, Canada
Residency-Pediatrics
Special Project: Electronmicroscopy of Heart Muscle

1968-1969 University of Oregon Medical School Hospital and Associated Clinics
Internship-Rotating

1964-1968 University of Southern California
School of Medicine
Medical Doctorate (MD)

1963-1964 University of Southern California
Graduate School
Master of Science in Biophysics (MS)
Nerve Action Potential Conduction

1961-1963 University of California, Los Angeles
Bachelor of Science in Chemistry
Radiation Chemistry

1959-1961 Reed College, Portland, Oregon

Employment:

Present Consultants in Epidemiology and Occupational Health, Inc.
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1980-1981 Chief Executive Officer
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1977-1980 Occupational Physician and Epidemiologist
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1976-1977 Private Practice of Pediatrics
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1974-1976 Senior Epidemiologist
Epidemiology Branch, National Institute of Child Health and Human Development
National Institute of Health
Bethesda, MD

1972-1975 Lecturer in International Health and Consultant in Family Planning
Development Administrators Training Program
University of Connecticut
Hartford, CT

1971-1973 Medical Director, Middletown Free Clinic
Middletown, CT

1970-1972 Epidemic Intelligence Service Officer from the Center for Disease Control
Atlanta, GA
Attached to the Connecticut State Department of Health, Department of Preventable Diseases and the Connecticut State Tumor Registry

1968 WHO/USPHS Smallpox Eradication Program
Kaduna, Nigeria

Consultant Activities:

1986 Consultant to the Halogenated Organics Subcommittee of Environmental Health Committee of the Science Advisory Board to the Environmental Protection Agency

1986 Senate Commerce Committee on Product Liability Hearing for the Committee on Commerce, Science and Transportation

1986 Department of Health and Human Services, Public Health Service, National Institute of Health on Small Business

1985 Consultant in Epidemiology (Gynecomastia in Haitians), U.S. Department of Justice

1985 Member, Epidemiology Study Section on small business incentive grants to National Institute of Health

1984 Consultant in Drug Effect Epidemiology (Teratology), U.S. Federal Court, Cincinnati, Ohio

1983 Consultant in Epidemiology, Office of Civil Rights, U.S. Department of Justice

1977 Consultant in Birth Defect Epidemiology, National Center for Health Statistics

1973 USAID Consultant in Family Planning Training for Korea, Thailand, Bangladesh, and Pakistan

1972 Vaccine Morbidity Studies in Amazonian Indians, Yale-PAHO

1971 Short-Term Consultant on Cholera to the Phillipines, World Health Organization

Honors:

American Academy of Occupational Medicine, Fellow 1987
American Occupational Medicine Association, Fellow 1985
American College of Toxicology, Associate Member 1984
American College of Preventive Medicine, Fellow 1983
American College of Preventive Medicine
Occupational Medicine 1983
Preventive Medicine 1975

American College of Epidemiology, Charter Fellow 1982
American Academy of Pediatrics, Fellow 1976
American Board of Pediatrics, 1975
Royal Society of Tropical Medicine, Fellow 1974
Annual Prize of the Society for Epidemiologic Research, May 1972

Teaching Experience:

Annual Lectures:
Occupational Medicine, Epidemiology, Teratology
Statistical Methods in Meta-analysis
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Committee Assignments:

1988 Chairman, AIDS in the Workplace Symposium, American Industrial Hygiene Conference

1985-Present Chairman, Occupational Medicine Committee
American Industrial Hygiene Association

1984-1985 Chairman, Occupational Epidemiology Committee
American Industrial Hygiene Association

1976-1978 Past Secretary-Treasurer
Society for Epidemiologic Research
2423 Tunlaw Road, N.W.
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1975 Chairman, Symposia on Bioethics in International Health,
APHA, Chicago, IL

Administrative Experience:

1981-Present President
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1977-1980 Director of Technical Services
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1976-1977 Private Practice of Pediatrics
Pleasant Hills, CA

1974-1976 Senior Epidemiologist
Epidemiology Branch, National Institute of Child Health and Human Development
National Institute of Health
Bethesda, MD 20892

Editorial Positions:

American Industrial Hygiene Association Journal
American Journal of Public Health
American Journal of Epidemiology
Public Health Reports

Memberships in Professional Societies:

1987-Present American Academy of Occupational Medicine
1987-Present International Commission on Occupational Health
1986-Present American Medical Association
1986-Present International Society of Regulatory Toxicology and Pharmacology
1984-Present Air Pollution Control Association

1984-Present American College of Toxicology
1983-Present American Occupational Medical Association
1983 American College of Preventive Medicine
1983-Present American Conference of Governmental Industrial Hygienists, Inc.
1982-Present American College of Epidemiology
1982-Present American Public Health Association
1980-Present American Industrial Hygiene Association
1976 American Academy of Pediatrics
1974 Royal Society of Tropical Medicine

Publications:

1. "Effects of Bilary Obstruction on Serum Amylase and Lipase Activity," Cucci, Hiyashi and Lamm, Epatologia, 12:829-36, September/October, 1966.
2. "Education Problems in U.S.A.," Lamm, Lancet, 1:839, April 18, 1970.
3. "Control of Salmonella Vector" - Editorial, Lowenstein, Lamm, Gangarosa, J. Infect. Dis., 124:433, October, 1971.
4. "Respiratory Distress Syndrome and Heroin Addiction," Sullivan and Lamm, Lancet, 1:155, January 15, 1972.
5. "Turtle Associated Salmonellois - The Magnitude of the Problem," Lamm, Taylor, Gangarosa, Anderson, Young, Clark and Bruce, Am. J. Epidem. 95(6):511-517 June, 1972.
6. "The Rationale for a Family Planning Program," a self-instructional unit, University of North Carolina, 1973.
7. "Analysis of Preliminary Health Data from Shanghai, 1972," Lamm and Sidel: a chapter in China's Health as Seen Today, Fogarty International Center, NIH, 1973, reprinted 1975.
8. "Measles Immunity in Children Vaccinated Before One Year of Age," Schluederberg, Lamm, Landrigan and Black, Am. J. Epidem., 97:402-9, 1973.
9. "Lead Content of Milk Fed to Infants: 1971-1972," Lamm, Glynn, Cole, and Ullman, New Eng. J. Med., 289(11):574-5, September 13, 1973. Reprinted in Nursing Digest 1975 Review of Community Health, pages 85-6, and Nursing Digest 1975 Review of Maternal Child Health, pages 18-20.

10. "Lead Contamination in Milk Fed to Infants: 1972-1973," Lamm and Rosen, Pediat., 53(2):137-141, 1974.
11. "Further Comments on the Lead Contents of Milk Fed to Infants," Rosen and Lamm, Pediat., 53(2):144-5, 1974.
12. "Cervical Cancer in China," Lamm, Brit. Med. J., 2:43, July, 1974.
13. "Genetic and/or Environmental Etiologies of Congenital Malformations: An Epidemiological View," Hoffman and Lamm, Am. J. Epidem. 102:456, 1975.
14. "Reactions to Rubella Vaccine and Persistance of Antibody in Virgin-Soil Populations after Vaccination and Wild-Virus-Induced Immunization," Black, Lamm, Emmons, Pinheiro, J. Infect. Dis., 133(4):393-8, April, 1976.
15. "Physiologic Evidence of Nutritional Adequacy in Primitive Amazon Indian Tribes," Am. J. Epidem., 104:353-3, 1976.
16. "Blood Lead Concentrations Among Formula-Fed and Breast-Fed Infants," Am. J. Epidem., 104:312, 1976.
17. "Nutritional Status of Brazilian Kayapo Indians," Black, Hierholzer, Lamm and Lucas, Hum. Biol., 49(2):139-53, 1977.
18. "Recording of Birth Injuries and Malformations of Infants," Lamm, Am. J. of Obst. Gynec. 125(6):879, 1976.
19. "An Unnecessary Risk to Children," Lamm Brit. Med. J., Sept. 4, 1976, 582.
20. "Reactions to Ruebella Vaccine and Persistence of Antibody in Virgin-Soil Populations After Vaccination and Wild-Virus-Induced Immunization," Lamm, J. Infect. Dis. 133(4):393-398, 1976.
21. "Time Trends in Cause-Specific Infant Mortality Rates - U.S.A., 1968-74," Lamm, Am. J. Epidem., 106:234, 1977.
22. "Etiologic Inquiries into U.S.A. Low Birth Weight Epidemic," Lamm, Am. J. Epidem., 106:234, 1977.
23. "The Design of a New Data Base for the Study of Congenital Malformation Epidemiology," Lamm and Leaverton, Proceedings of the Am. Pub. Hlth. Assoc. Meeting, 105:119, 1977.
24. "Benzene and Leukemia," Tabershaw and Lamm, Lancet, 11:867-8, 1977.

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26. "An Etiologic Interpretation of Birth Defect Incidence Rates in Twin Pairs," Lamm and Hoffman, Progress in Clinical and Biological Research, 24 Pt B:143-48, 1978.
27. "The Feasibility of Using U.S. Birth Certificates to Test Occupational and Environmental Hypotheses of Birth Defects Etiology," Lamm, The Public Health Conference on Records and Statistics, the People's Health: Facts, Figures and the Future, DHEW Pub. No. (PHS) 79-1214, August, 1979, Hyattsville, Maryland, 102-4.
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29. "Health Hazards of Formaldehyde," Berger and Lamm, Lancet, 1:1264, 1981.
30. "Upper Respiratory Irritation Symptoms and Formaldehyde Exposure Levels Among Mobile Homes Residents," Lamm, In: Berglund B., Lindvallt, Sundell J. eds. Indoor Air, 3:361-366, 1984.
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32. "Inorganic Arsenic: The Importance of Accurate Exposure Characterization in Risk Assessment," Lederer and Lamm, In: Whipple C, Covello VT eds. Risk Analysis in the Private Sector, New York: Plenum Press, 1985; 149-163.
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34. "Irritancy Levels and Formaldehyde Exposures in U.S. Mobile Homes," Lamm, In: Walkinshaw DS ed. Indoor Air Quality in Cold Climates: Hazards and Abatement Measures Pennsylvania Air Pollution Control Association, 1985;137-47.
35. "Physicians' Accuracy for Diagnosing Sore Throats," Lamm and Linn, JAMA 1986;255(6):746-747.
36. "Gynecomastia Among Ethiopian Jews," Linn, Almagor, and Lamm, Pub. Hlth. Rpts 1986;101(3):237. 37. "Indirect

Exposures: The Significance of Bystanders at Work and at Home, Lamm, S., Am. Ind. Hyg. Assoc. J., 47(12):A-754, 1986.

38. "Cadmium and Prostate Cancer: Pooling the Data from Updated Studies," S.H. Lamm, La Medicina del La Voro, 77(1):111, 1986.
39. "Analysis of Mortality Studies of Globe, Colorado Cadmium Workers," S. Lamm, Cadmium 86, Edited Proceedings, Fifth International Cadmium Conference San Francisco; 120. 1986.
40. "Industrial Hygiene Involvement in Occupational Epidemiology," Checkoway, Dement, Fowler, Harris, Lamm and Smith, Am. Ind. Hyg. Assoc. J. 1987; 48(6):515-523.
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43. "Comparative Risk and Benefit Analysis of Alternative Remedial Plans For An Arsenic-Contaminated Industrial Site," S.H. Lamm, S. Tirey, Managing Environmental Risks Air Pollution Control Association 1988, 38-60.
44. "Comparative Carcinogenicity of the PNAs As A Basis For Acceptable Exposure Levels (AELs) in Drinking Water," P.J. Rugen, S.H. Lamm, Regulatory Toxicology and Pharmacology, 1988 (in press).
45. "Epidemiologic Inconsistencies Underlying the Quantitative Assessment of Leukemia Risk from Benzene Exposure," S.H. Lamm, A.S. Walters, R. Wilson, D.M. Byrd, H. Grunwald, Env. Health Perspectives, 1988 (in press).
46. "Lung Cancer and NNRD Mortality Similarities of Vermont and New York State Talc Workers," Lamm, S.H. Starr, J.A. Proceedings of the VIIth International Pneumoconioses Conference, August, 1988 (in press).

Revised 10/4/88

UNITED STATES DISTRICT COURT
For the District of Georgia

No. CV-484-118

DAVID AND BARBARA WILL, et al.,
Plaintiffs,

v.

RICHARDSON-MERRELL, INC.,
Defendants.

Deposition of STEVEN H. LAMM, a witness of lawful age, taken on behalf of the Plaintiffs in the above-entitled cause, pursuant to agreement of counsel, before Harlyne S. Blum, Notary Public, in the law offices of Paulson, Nace & Norwind, 1818 N. Street, N.W., Washington,D.C. 20036, at 1:10 p.m., Friday, December 27. 1985.

APPEARANCES:

BARRY J. NACE, Attorney-at-Law
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Counsel for Defendant

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teratogen in the absence of evidence from the laboratory.

In the same sense -- what I mean by "level of proof," I would say that it was generally accepted that epidemiology has demonstrated that cigarette smoking causes lung cancer. There are certain people who will not accept that totality of that information as so indicated. Nonetheless, I think that the evidence is quite strong, and based on that, one can say that cigarette smoking is quite capable of causing lung cancer.

Q. Would you agree that in some instances of trying to determine whether or not a drug is capable of causing a birth defect, that it would be helpful to utilize epidemiologic studies and other scientific evidence that is available?

A. I'm bothered by the use of "capable."

Q. I know you are. Go ahead. You can answer the question.

A. I forgot the question.

Q. I probably did, too, Doctor.

Q. Would you agree that it would be useful then, in trying to determine whether or not Bendectin is capable of causing a birth defect in humans, to utilize epidemiological evidence as well as other available scientific evidence?

THE WITNESS: Would you read back the question?

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(The pending question was read by the reporter.)

THE WITNESS: Yes.

BY MR. NACE:

Q. Would the other available scientific evidence include animal studies?

A. At times.

Q. Would it at times include knowledge of the structure and activity of a particular component of the drug?

A. It might.

Q. Might it also include knowledge about in vitro studies that were done?

A. I'm not sure what you mean by "in vitro studies," specifically, but it might.

Q. Might it also include information about a drug that

might come from the company's own files as opposed to formal epidemiological studies?

MR. WOODSIDE: Object to the vagueness and general nature of the question. Go ahead.

THE WITNESS: Valid information is always useful.

BY MR. NACE:

4. Excerpts from deposition of John Davis Palmer, Ph.D., M.D., (Ex. C to Deft.'s Mot. for Summ Judg.), filed Aug. 3, 1989

UNITED STATES DISTRICT COURT
Southern District of California

NO. 84-2929-G(I)

MICHAEL SCHULLER, ANITA DE YOUNG, and ANITA DE YOUNG as Guardian Ad Litem for ERIC SCHULLER, a Minor

Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., a Delaware Corporation (successor to RICHARDSON-MERRELL, INC.) and DOES 1 through XX., inclusive

Defendants.

No. 84-2013-G(I)

WILLIAM DAUBERT and JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT and JESSICA DAUBER, Minors,

Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., et al.,

Defendants.

DEPOSITION OF JOHN DAVIS PALMER, M.D.
December 16, 1988, Tucson, Arizona

WOPPERT, HAIGHT, BRUNOTTE & GARCIA
Certified Court Reporters
10 East Broadway, Suite 10
Tucson, Arizona

[15]
may be four months or it may be six. I don't remember for sure.

Q. You mentioned that you had done studies with human beings. Have you ever designed an epidemiology study?

A. No.

Q. Have you ever published an epidemiology study?

A. No.

Q. Have you ever designed an epidemiology study?

A. No.

Q. Who has funded your research over the years?

A. At the University of Minnesota as a graduate student my research was funded by the Sterling Winthrop Pharmaceutical Company and in part by the National Institutes of Health. They supported my salary as a fellow in the combined M.D./Ph.D. program.

At the University of Colorado my research was funded by institutional funds which probably had an origin from the National Institutes of Health, part of an institutional grant that's awarded based on the amount of the support that institution received from the NIH. But that was institutionally administered money,

* * *

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but these two papers and the abstract form the basis of the opinion that I have been able to give you this afternoon.

Q. What published epidemiological studies support your opinion that Bendectin causes limb defects?

A. With respect to humans, I mean, published studies with the studies done with humans or published studies of another

nature, animal studies vis-a-vis the drug may cause limb reduction.

Q. Right now my question is just with respect to the published human epidemiological studies. Which of those support your opinion that Bendectin causes limb defects in humans?

A. I don't believe any of them directly address that issue and find a positive association by the scientific criteria that are used by those authors. Yet, almost all the authors, and in particular the Boston group, make statements in their papers or in subsequent responses to letters to the editor and communications of that type that their analysis of the data and using techniques of the type employed, do not exclude the possibility of an association between the use of Bendectin and a variety of other defects, implied limb defects as well.

MR. NACE: I want to enter an objection. I

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assumed that your question dealt only with whether there were any papers specifically on limb reduction defects that enable limb to form an opinion on the reduction defects, is that what you were asking?

MR. MESSER: That wasn't the question.

THE WITNESS: Then I misunderstood your question.

BY MR. MESSER:

Q. Are there any published epidemiological studies that conclude Bendectin causes limb defects in humans?

A. Not that I know of.

MR. NACE: I am going to object until you define what you mean by the word conclude. You mean beyond a reasonable doubt, sir, or within a reasonable degree of certainty, or do you mean within ninety-five certainty?

I think your question is improper, irrelevant, immaterial and designed to trick the witness.

THE WITNESS: I do not believe the word conclusion is used in the papers. Ordinarily in papers of the type that we're talking about where there is a hypothesis vis-a-vis exposure in the development of a defect, the authors when they find a negative result, in

* * *

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Q. But you have never done a study in the field of teratology, have you?

A. That's correct.

Q. Never published anything in the field of teratology?

A. That's correct.

Q. Have you ever done any study on Bendectin?

A. No.

Q. Have you ever done any study on doxylamine?

A. No.

MR. NACE: I have to object. What are we talking about by "study"? I mean, you may have misled the doctor.

THE WITNESS: I have never published any reports on Bendectin or doxylamine. I have studied the literature.

BY MR. MESSER:

Q. But you have never done any laboratory or clinical-type investigation with Bendectin on doxylamine, have you?

A. That's correct.

Q. Isn't it true, Doctor Palmer, that none of the published epidemiological studies states that Bendectin causes birth defects?

A. No.

* * *

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asked.

Q. What doctors at the University of Arizona consult on birth defect cases with respect to causation?

A. I don't know.

Q. Do you know of any doctors at the university who consult with parents who have had a child with birth defects?

A. I'm sure there are some, but I don't know who they are.

Q. Do you know what field they practice in?
A. No, I could only speculate.
Q. But you are not one of those doctors?

A. I don't deal with the parents of my patients. I do have parents who have birth defects of one type or another and once in a while we discuss those issues with those patients.
Q. Have you given a patient an opinion about the cause of a birth defect?
A. I'm sure I have when it comes to adults with certain types of birth defects, but I don't recall any specific examples.
Q. Have you ever consulted with a patient and advised him that the cause of his birth defect was exposure to a drug?
A. Not to my recollection.
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Q. Have you ever advised a patient that the cause of the birth defect was exposure to any chemical or other environmental agent?
A. Not to my recollection.
Q. Now, are you aware that Bendectin or Debendox, D-e-b-e-n-d-o-x, has been approved for use in Britain?
A. Yes.
Q. Are you aware that the British government has looked into Bendectin and did not find it to be unsafe?
A. No.
Q. Do you disagree with the position taken by the British authorities as to the medical evidence pertaining to Bendectin?
MR. NACE: Objection. Do you want to tell us what the position is? Do you have a document?
THE WITNESS: If it's a position, to-wit: That this drug is safe for administration to gravid females, I disagree with that.
BY MR. MESSER:
Q. And are you aware that the West German government has approved the use of Bendectin?
A. No.
Q. And if they had, would you disagree with

* * *

5. Affidavit of Stuart A. Newman, Ph.D (Dock. No. 184), filed Sept. 28, 1989

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UNITED STATES DISTRICT COURT
Southern District of California

No. 84-2013-G(I)

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and As Guardian Ad Litem for JASON DAUBERT, a Minor,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50 Inclusive,
Defendants.

NO. 84-2929-G(I)

MICHAEL SCHULLER, ANITA DE YOUNG, and ANITA DE YOUNG as Guardian ad Litem for ERIC SCHULLER,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50., Inclusive
Defendants.

[2] **AFFIDAVIT OF STUART NEWMAN, P[h].D.**

Stuart A. Newman, Ph.D. states as follows:

1. I am a member of the Department of Cell Biology and Anatomy, New York Medical College, Valhalla, New York where my duties include teaching and research. My curriculum vitae is attached. I have particularly been involved in research on the development of the limb, in which area I have concentrated my work for approximately 17 years. I have received several research grants with respect to my work on limbs.

I have received my degree with my major in chemistry from Columbia University and received my Ph.D. from the University of Chicago. During my Ph.D. training I received courses in chemistry, physics, biology and I did original research. I did work on how chemistry explains biological systems and how chemistry relates to how cells work. Specifically my doctoral paper involved the subject of how chemistry can explain how living systems work. I received further training at the Marine Biological Laboratory at Woods Hole, Massachusetts where I studied embryology and received a certificate in embryology from the Marine Biological Laboratory which is one of the foremost research and teaching institutes in the country with respect to the

fields of embryology, physiology and marine biology. I specifically studied embryology which is the study of how embryos develop. (A very small number of people are
[3]
selected to attend the Woods Hole program.)

I have taught numerous chemistry courses and have held all the ranks from instructor to where I am currently a full professor in the Department of Cell Biology and Anatomy, and I have taught histology, cell biology, etc. I also teach laboratory techniques and lecture to medical students. I have been a research fellow at the University of Sussex in England, where I was a visiting fellow in the Department of Biological Sciences and I conducted independent research supported by the British government. I have taught courses in molecular biology and cell development. Molecular biology is basically the study of how cells regulate the synthesis of their various components. Developmental biology is a specialized area that has to do with tissues as they change their shape and their form and change their type, which particularly involves the embryo and how the body is taking form.

I am also a member of the Department of Medicine at the New York Medical College. My current duties include directing the histology courses and directing a laboratory where we do developmental, cell, and molecular biology, specifically including work on the development of the limbs.

I have served as a consultant to the National Institute of Health where I serve on a panel to help determine what funds are awarded for research. I have been a peer reviewer for the National Science Foundation and a consultant to
[4]
several scientific journals and magazines and published articles that result from scientific research. I have specifically been a peer reviewer for Cell, Developmental Biology, Science, Cell Differentiation, Nature, Differentiation, and several others. I have published more than 40 articles myself, many of which involve the limb as the major subject. I have lectured to other doctors with respect to limbs and how they form on more than 70 occasions in the United States and abroad. I have been keynote speaker at the British Society of Developmental Biology Meeting

on the development of the limbs. I have also published approximately 10 chapters in text books, some of which deal with limb development.

I have done in vitro studies which are basically the way scientists now have to look at systems, and parts of the body in isolation from other parts of the body to understand how tissues behave. The in vitro studies that I have done have primarily involved limb tissues. These in vitro studies are generally and reasonably relied upon by developmental biologists to try to determine how the body develops and are the most modern scientific tool on the subject. In vitro studies are also generally used and relied upon to help determine what causes human bodies to not develop the way they would normally develop. I am familiar with antihistamines and how they affect the cells from my scientific background, my reading of the scientific

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literature and general understanding in the field of biology and biological chemistry.

My Ph.D. is in the field of chemical physics. I do research on the causes of birth defects. I am frequently consulted by physicians with respect to sharing my expertise on the cause of birth defects.

My work specifically relates to the area of teratology (which is the study of abnormal development) because if one is trying to understand the mechanisms of normal development, one must also understand the mechanisms of abnormal development.

2. Utilizing the type of data that is generally and reasonably relied upon by scientists who are trying to determine whether a drug is teratogenic, it is my opinion within a reasonable degree of scientific certainty that the antihistaminic component of Bendectin, doxylamine succinate, is a teratogen. That means that it has the capability of affecting the normal development of cells in the human embryo and thereby causing abnormalities. Specifically, it is my opinion within a reasonable degree of scientific certainty that the antihistaminic component of Bendectin, doxylamine succinate, is capable of causing abnormal development of the limb in the human. This includes abnormal (which includes lack of) development of the bones, muscles and other portions of the

limb.

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3. The development of the limb in the human is basically the same as in other animals including chickens, birds, monkeys, rabbits, rats, dogs, etc. The development of the limb involves a process called chondrogenesis which is the formation of cartilage. The entire limb structure is laid out as cartilage and only after that occurs does it begin to change into bone. Part of the process of chondrogenesis is the cell to cell communication that takes place which affects how the cells act and react. This is a chemical process. Both proteoglycan and collagen are important materials in the development of the process of chondrogenesis. Mesenchyme cells have neither cartilage type collagen nor cartilage-type proteoglycan which can be measured. It is only after mesenchyme cells communicate with each other that they begin to make new materials and that you can then detect proteoglycan and collagen. In vitro studies specifically can analyze and measure the development of the foregoing. Proteoglycan is necessary in order to cement cells together - without it, structures of the limb may be missing or improperly formed.

4. A teratogen is a substance that causes abnormal development and chemicals including drugs may be teratogens.

We know that doxylamine succinate, a component of Bendectin is, an antihistamine. Antihistamines have similar characteristics. Specifically there is a strong similarity between doxylamine succinate and the drug Benadryl, another

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antihistamine. Numerous articles have been written concerning the findings of antihistamines on pregnancy. These include articles by Shelesnyak, McKay, King, and others. The findings were that antihistamines may damage the fetus. It is important to scientists in determining how one antihistamine will act to know how others would act, so that knowledge about one antihistamine or a particular class is helpful in understanding other antihistamines of the same or similar classes and it is helpful in determining such actions. The kinds of defects in fetuses that were found with antihistamines include limb defects, cleft palate defects and the like.

5. All of the foregoing articles and data are helpful in determining whether or not a particular antihistamine would be capable of being a teratogen and effecting the development of the body and the limbs in particular and is the type of data that is generally and reasonably relied upon to help determine teratogenicity.

6. Scientific articles and work by Hassell and Horigan; Guntakatta; Budroe; BGA; all deal with in vitro studies concerning doxylamine succinate and Bendectin. In vitro studies are generally and reasonably relied upon to help determine the teratogenicity of a substance and have been used for the purpose of studying how limbs develop and why they develop abnormally or not at all. One of the outstanding articles (Hassell and Horigan) was conducted at

[8]

NIH and shows that Bendectin and doxylamine succinate have the ability to interfere with the growth or differentiation of cells and reduces the amount of proteoglycan available. The technique used by Hassell and Horigan is one that is generally and reasonably utilized for these purposes and is a verified technique.

Guntakatta's results are concordant with Hassell and also shows the effect of Bendectin on DNA. The BGA study shows that Bendectin has the ability to cause chromosomal breakage which is another indication that the substance is toxic or poisonous to the cell. The BGA study shows chromosomal abnormalities in the presence of Bendectin. There is in fact a relationship between the concepts of mutagenicity and teratogenicity in that one would reasonably rely upon both kinds of studies to help determine whether or not a drug is a teratogen because it would tell whether or not the drug is toxic to cells. The Budroe study also shows that the doxylamine succinate component of Bendectin had the ability to damage DNA.

Based on the various in vitro studies that have been performed including the ones identified previously within a reasonable degree of certainty Bendectin and doxylamine succinate, its antihistaminic component, interferes with a number of aspects of the cell. It interferes with the conduction of nerve cells, DNA synthesis, damages DNA to cause unscheduled DNA synthesis, and reduces the amount of

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proteoglycan formed during the process of chondrogenesis. It is in fact therefore toxic to the normal maintenance of properties of cells. This data further shows within a reasonable degree of scientific certainty that doxylamine succinate and Bendectin have the capability of interfering with normal limb development in the human.

7. It is my opinion based upon my education, training, and experience, specifically with respect to my experience with limb development, utilizing the in vitro studies and the pharmacology aspects of Bendectin that are known to me and is known to others including the fact that doxylamine succinate is an antihistamine which is a lipophilic, amphipathic substance that Bendictin is capable of interfering with the development of the limb in the human being and causing birth defects in the developing limb of the human being and that Bendectin is a human teratogen in the normal therapeutic dose.

8. I have further reviewed animal studies including those by Dr. Rolle, by RTI and the company studies and they also are helpful in determining the teratogenicity of Bendectin and in my opinion within a reasonable degree of scientific certainty support the in vitro studies and enable one to conclude that Bendectin (and its component doxylamine succinate) does in fact have the ability of being a teratogen in a human being at normal therapeutic doses.

[10]

9. The type of science that I have been describing thus far is generally laboratory science which is considered a hard science in that its conclusions are not substantiated in the basis of statistical inference as much as upon controlled experiments where individual variables or components are changed only in a very precise fashion as opposed to epidemiology studies (which is known as a "soft science" because of the extreme numbers of variables that are involved). True scientists who deal with the subjects encompassed herein, namely developmental biology would not rely solely upon epidemiological data to draw conclusions about the ability of a chemical, e.g. drug, to affect the cells in the developing human fetus.

Moreover, it is not only proper, but common practice to make inferences about how drugs are going to affect humans and have affected humans based upon pharmacology data, animal studies, and in vitro studies. Such data are all of the type that is generally reasonably relied upon to help determine whether or not a drug is capable of causing an effect in a human being, such as a teratogenic effect. It is this type of data, as described heretofore, along with my education, training, and many years of experience that permits me to conclude that Bendectin and its component doxylamine succinate are teratogenic and thereby capable of adversely affecting the development of cells in the human fetus whereby abnormalities including defects occur.

[11]

Moreover, it is my opinion within a reasonable degree of certainty based on all of the foregoing that Bendectin is in fact teratogenic in the human being at the normal human therapeutic dose.

/s/
Stuart A. Newman, Ph.D.

Sworn to and subscribed in my presence on this 22nd day of September, 1989.

/s/
Notary Public

My commission expires:
1/31/91

[SEAL]

6. Affidavit of Frederick Crescitelli, Ph.D, and curriculum vitae (Dock. No. 183), filed Aug. 22, 1989

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UNITED STATES DISTRICT COURT
For the Southern District of California

NO. 84-2013-G(I)

WILLIAM DAUBERT; JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT, a minor,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50 inclusive,
Defendants.

NO. 84-2929-G(I)

MICHAEL SCHULLER, ANITA DE YOUNG, and ANITA DE YOUNG as Guardian Ad Litem for ERIC SCHULLER,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES I through XX., inclusive
Defendants.

[2] **AFFIDAVIT OF FREDERICK CRESCITELLI**

Frederick Crescitelli states as follows:

1. I am emeritus professor of biology at the University of California in Los Angeles where I have been a professor since 1949. I have a Ph.D. in biology and bio-chemistry and an honorary medical degree from the University of Linkoping in Sweden. I received my Bachelors Degree in 1930 from Brown University, a Masters Degree in 1932, and a Ph.D. in 1934. I received a Phi Beta Kappa, Sigma Psi and Williams Keene Award University for research work. I was graduated summa cum laude. I have had a National Science Foundation Senior Fellowship and a fellowship to work at Johns Hopkins University.

My profession is as a scientist and biologist, and I have
taught at Brown University, University of Iowa, University of Washington, Stanford University, University of Southern California, University of California, Los Angeles, Johns Hopkins University, University of London, and the University of Cologne in Germany. During all of this time I was teaching but was also involved in research. I am a member of numerous scientific associations, including the Federation of American Biologists, the American Association of Scientists, the American Association for the

Advancement of Science, the American Academy of Neurology, the Biophysical Society, and others. I have served on numerous advisory committees of NIH. My undergraduate training is in biology with accessory
[3]
training in physics and chemistry; my Masters Degree is in biochemistry and my Doctorate Degree is in physiology. All my biologic work has been either biochemical in nature, pharmacological in nature, or physiological in nature, and I have worked with all kinds of animals. The purpose for doing the research in animals is for a greater understanding of the physiology of man. I have approximately 125 formal papers, 80 to 100 short notes or abstracts, and a half-dozen reviews. A copy of my curriculum vitae is attached.

I have authored articles concerning antihistamines and related compounds and their effect on nerve fibers.

I have further specifically performed studies on the substance known as doxylamine succinate, an antihistamine. I have further reviewed the pharmacological data and animal studies, as well as in vitro studies pertaining to Bendectin and doxylamine succinate.

2. It is my opinion, within a reasonable degree of scientific certainty, that based upon my education and training and experience, my own work, and my review of the scientific literature, that Bendectin and doxylamine succinate (its antihistaminic component) is a teratogen. That is, it is a chemical that is capable of affecting the development of cells in the human fetus at normal therapeutic doses.

Moreover, our study shows that doxylamine succinate has the ability to block nerve conduction. More specifically, it is my opinion, based on the, foregoing, that antihistamines,
[4]
within a reasonable degree of scientific certainty, produce irreversible damage to nerve fibers. This includes the antihistaminic substance doxylamine succinate.

It is well accepted in the scientific field that a substance such as doxylamine succinate is capable of reaching the fetus and passing through the placenta. Moreover, doxylamine succinate is an amphipathic substance, which means it orients itself in water - fat layers, and that, specifically, the human embryo during the first

trimester is a complex multi-molecular system with fatty material. Antihistamines, in particular, are known to get into cells rather easily, in part because of their relatively small molecular weight.

3. I must point out that at the cellular and molecular levels the qualitative effects obtained in carefully designed and confirmed experiments will be the same regardless of the organism employed. Whether one uses a human, a monkey, a rabbit, a frog, or a fish, the fundamental responses will be qualitatively the same so the interpretations made from experiments on species A are applicable to species B. There are so many examples of this fundamental truth that the point need not be labored. DNA, for example, is the genetic material for all organisms. ATP is the energy-releasing compound of universal applicability. Nerve conduction is the same process in squid and man. Muscle contraction involves the same molecular reactions in ali vertebrates. The chemical

[5]

transmitters of the nervous system are functional elements in vertebrates and in the few invertebrates that have been investigated. Belief in this dogma - for dogma it is - has led to the advances in biology and medicine that we know today.

The concentration of a drug in the bulk phase of a system of living cells is not necessarily the same as the concentration at or within the cells of that system. Many reagents are preferentially absorbed to cell surfaces so as to achieve local concentrations well above that of the bulk phase. This is especially true of substances having amphipolar structure, i.e., a lipophilic structure at one end and a hydrophilic moiety at the other end. Such is the structure of many antihistamines, including doxylamine.

An important point worth noting is that the very early fetus is quite a different organism than the mother or the late embryo. Neither the liver, with its detoxifying mechanisms, nor the kidneys, with their homeostatic regulating power, are present so that the organism is at the mercy of agents reaching it via the placental circulation, including doxylamine.

4. The two antihistamines that are most closely related structurally, physiologically, and pharmacologically, are Benedryl and doxylamine succinate.

It is my opinion, within a reasonable degree of scientific certainty, therefore, that studies that have been conducted on Benedryl and data obtained from such studies are

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also quite applicable to doxylamine succinate.

5. Based on my education, training, experience, and the studies that I have performed, plus the medical literature and scientific literature, it is my opinion, within a reasonable degree of scientific certainty, that doxylamine succinate is a teratogen in humans; that it interferes with nerve function which is necessary for normal development of muscles and limbs and other structures of the body; and it has the ability to, in fact, effect the development of limbs in the human. Moreover, this is a physiological problem which is the subject of biology, anatomy and pharmacology. This is an area that I have worked with for 30 to 40 years. Moreover, it is my opinion that in the normal therapeutic dose, Bendectin and its compound doxylamine succinate is a teratogen.

6. I have further reviewed the in vitro studies pertaining to Bendectin and they also add to our scientific knowledge of Bendectin and its antihistaminic compound, or doxylamine succinate, and they are also helpful and generally and reasonably relied upon to help determine teragenocity and, in fact, the in vitro studies pertaining to Bendectin and doxylamine succinate do show that Bendectin and doxylamine succinate are teratogenic.

Moreover, animal studies are also helpful and generally and reasonably relied upon to help determine whether or not a drug is teratogenic and capable of affecting the human cells and the animal studies on Bendectin and doxylamine succinate,

[7]

indicate within a reasonable degree of scientific certainty that Bendectin and its component doxylamine succinate are teratogenic in the human.

7. Moreover, it is scientifically improper to rely solely upon epidemiology studies to determine whether or not a drug is a teratogen. One of the primary reasons for that is that epidemiological studies are generally inconclusive because of the subjective nature of the studies and the variables that are involved. No teratogen has been discovered through an epidemiological study and it is absolutely incorrect to assert that they are the best evidence

on the subject. It is further clear that, in fact, they are the least reliable data of all the data available on Bendectin.

8. In summary, it is not epidemiological studies that scientists rely upon to determine whether or not a drug is a teratogen. Much better scientific data includes pharmacology data, animal studies, and in vitro studies. This is the type of data generally and reasonable relied upon to determine if and how a substance is going to have a toxic effect upon a cell and it is the developing cells that determine whether or not the human body will develop normally or abnormally. Using the available scientific data, i.e., the pharmacologic data, the animal data, and the in vitro studies, including my own

[8]

study on antihistamines, it is my opinion, within a reasonable degree of scientific certainty, that doxylamine succinate is a teratogenic substance capable of producing abnormalities in the human fetus, when ingested at normal theraputic doses.

/s/
Frederick Crescitelli

STATE OF CALIFORNIA
COUNTY OF LOS ANGELES

Subscribed and sworn to before me this 26 day of September, 1989

/s/
Notary Public

[Official Seal]

/s/
My Commission Expires

CURRICULUM VITAE

FREDERICK CRESCITELLI

Born:
June 23, 1909, Providence, R.I.

Education:
Brown University, Ph.B. 1930
Brown University, Sc.M. 1932
Brown University, Ph.D. 1934

Honors:
Phi Beta Kappa, 1932
Sigma Xi, 1932
Summa Cum Laude, 1934
Carpenter Premium, 1934
Keen Fellow, Brown University 1934-1935
Mellon Fellow, Johns Hopkins University 1946 (six months)
National Research Science Fellowship 1934
Senior Fellowship, National Science Foundation 1959 - 1960.

Positions:
Colby Junior College 1935-1936
Research Associate, University of Iowa, 1936-1940
Instructor, Department of Physiology, University of Washington, Seattle, 1940-1941
Acting Assistant Professor, Department of Physiology, Stanford University, 1941-1943.
Visiting Assistant Professor, Aviation Medicine, University of Southern California, 1943-1944
Medical Research Center, Edgewood Arsenal, Maryland, 1944-45
Fellow, Wilmer Institute, Johns Hopkins University, 1946
Associate Professor and Professor, University of California, 1946-present

Sabbatical leave to University of Cambridge, England, 1952-1953
Sabbatical leave to Institute of Ophthalmology, London, England 1959-1960.

Member of Societies:

American Society of Zoologists
American Physiological Society
Optical Society of America
American Association for the Advancement of Science
Biophysical Society
Association for Research in Ophthalmology
American Academy of Neurology

Committees:

Research Counsel, San Diego Zoological Society
National Counsel to Combat Blindness
Study Section, U.S. Public Health Service
Committee on Vision, National Research Council
Editor, Vision Research

Research Interests:

Insect metamorphosis
Insect metabolism
Nerve physiology and pharmacology
Physiology of vision
Biochemistry of vision
Color vision

Family:

Married to Fiona Clyde
Three children:
Richard, 13 M
Monica 10
Adrian 7

Publications:

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7. Affidavit of Adrian Gross, D.V.M. and curriculum vitae (Dock. No. 185), and excerpts of testimony in *Ealy v. Richardson-Merrell, Inc.* (Ex. 26 to Pltfs.' Opp. to Summ. Judg.), filed Aug. 22, 1989, and Sept. 28, 1989

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UNITED STATES DISTRICT COURT
For the Southern District of California

NO. 84-2013-G(I)

WILLIAM DAUBERT; JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, a Minor,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50 Inclusive,
Defendants.

NO. 84-2929-G(I)

MICHAEL SCHULLER, ANITA DE YOUNG, and ANITA DE YOUNG as Guardian ad Litem for ERIC SCHULLER,

Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50. Inclusive,

Defendants.

[2] **AFFIDAVIT OF ADRIAN GROSS**

1. My name is Adrian Gross. I am a veterinarian. After my four year combat service in the British Army, I matriculated in 1946 at the University of London, England, and then received my Bachelor's Degree at the University of Manitoba in 1949. I did additional postgraduate work at the University of Manitoba and then received my DVM degree and veterinary surgeon degree, in 1954. I then proceeded to do advanced pathology training at Ohio State University where I received a Masters' Degree in pathology and completed veterinary pathology courses. After that I took a number of postgraduate courses in statistics and biometry at the Michigan State University. Biometry is a branch of statistics that deals with measurements arising in biological fields. The M.Sc. degree from Ohio State was in pathology which involved the study of the disease process in animals and humans. I have been licensed to practice veterinary medicine continually since 1954. I was subsequently accredited by the United States Department of Agriculture in the field of veterinary medicine.

As concerns pathology, I have been employed as a pathologist with the United States Public Health Service, and in private research organizations. I then became Chief of Pathology of the Food and Drug Administration in 1964 and held several other positions there during the next 15 years. I began my service with the FDA in 1964

as Chief of

[3]

Pathology which involved supervision of a number of professional pathologists, (both physicians and veterinarians) who were engaged in examination of tissues during autopsies on animals. Following this, I next became the Deputy Toxicological Advisor. Toxicology is the medical discipline that deals with the adverse effects on health elicited by poisons. I then became the Assistant Director for Program Coordination which involved coordinating research on the safty of drugs. After that I became the Associate Director for Preclinical Investigations which required me to go around the country and supervise other scientists and audit toxicology studies. An audit is a process where one looks into the reliability of reports submitted to the FDA by the manufacturers of drugs. Our duties involved in the most paramount fashion examining the reliability of reports on research for the purposes of safety of drugs. An audit is an investigation where the reliability of reports is assessed at the site where the report has been prepared, i.e., in the laboratories of the manufacturers. The duties included examining the laboratory notebooks of raw observations and making sure that all observations were promptly and fully reported, checking of the facilities, checking the equipment and checking out the laboratory. My position required that I be satisfied with the way the operations were being run at the various laboratories, that the technicians knew what they were

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doing, and checking on credentials, training, supervision of the personnel involved in such studies.

Thereafter I transferred at the Environmental Protection Agency where I became Chief of the Toxicology Branch where I supervised many toxicologists. In 1980 I was promoted to Senior Science Advisor, a position I still hold.

I am giving this affidavit as I have given testimony on Bendectin in the past purely as a citizen and not as a representative of the United States Government.

I have been credited with a number of publications in the field of pathology and statistics but that is not the principal function of either the FDA or the EPA.

I am a member of the American Statistical Association, and

during my career with the FDA and the EPA I have consistently used formal statistical analysis of toxicology results; the aim of such analyses is to determine the relationship of a drug to a toxic effect.

I have also had training in embryology.

I am familiar with the subject of teratology because it encompasses the same areas that I have worked in during my career including embryology, pathology, statistics, and teratology. Teratology testing is simply another kind of toxicity test which focuses on events very early in life and shortly after birth.

I have as part of my duties analyzed data that have been collected for the purpose of determining whether or not

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a drug causes birth defects. That has been my function with the government in the past. In my experience with the government I have received commendations and awards from the United States Government including the Commissioner of Food and Drugs and various members of Congress.

2. I have performed an evaluation of the results arising in various animals studies that have been done involving the drug Bendectin and its components and in so doing I have utilized the methods and methodology that would generally and reasonably be accepted by those people who deal in the areas of evaluation of drugs for safety purposes and for toxicity purposes and for teratology purposes. I have reviewed what has been represented to me as being all of the animal studies pertaining to Bendectin and its components that were performed by Richardson Merrell, a/k/a Merrell-Dow. Those studies bear the numbers 63-01, 63-02, 63-27, 63-28, 63-29, 66-01, 66-02, 66-05, 66-07, 66-12, 75- 12, 75-13. I have also reviewed laboratory notebooks bearing the numbers 401T and 458T which pertain to studies 63-28 and 66-05. I have further reviewed animal studies performed outside the premises of Merrell known in this litigation as the following studies: "Rolle"; "RTI"; "McClure"; "Hendricks I and II"; and others. I have also reviewed data that were submitted by Richardson-Merrell, a/k/a Merrell Dow, to the FDA and various other memoranda.

I have further submitted a detailed analysis

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of the results arising in such studies to counsel representing all parties to this action.

3. It is my opinion within a reasonable degree of certainty that from reviewing the animal studies identified previously and based upon my experience, education and training and utilizing the methods and methodology that are generally and reasonably relied upon by anyone analyzing such studies for the purpose of determining whether or not a drug has a toxic effect, or a teratological effect that the doxylamine succinate component of Bendectin is in fact a teratogen. By that I mean that it is capable of causing birth defects.

It is also standard practice in analyzing such animal data to do statistical analysis of the type that I have performed. Basic textbooks on the subject of teratology, such as Wilson's Handbook of Teratology, clearly show that a teratogenic effect or a toxic effect manifests itself by death, malformation, growth retardation and functional disorder. These are the manifestations of abnormal development which is caused by toxic substances such as teratogenic agents.

4. The purpose of doing animal studies is to determine as best as one can what will be the likely results in the human. There are a number of well-known reasons for studies in humans to have only limited usefulness in the process of establishing the safety of new drugs. It is

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largely due to this reason that studies in animals become critically important in this respect. One can then utilized one's education, training and experience by using generally and reasonably accepted methodology in an analysis to reach an opinion as to whether or not the drug would be a toxic substance or a teratogenic substance in the human. Animal studies in such a setting are not performed for the express purpose of determining the effect of a teratogenic agent on the animal, but rather on the likely safety of the agent for the human.

Further, the evaluation of results from a teratology study are in no way different from the evaluation of the results of any other toxicological study. The techniques that one uses are identical.

5. Having reviewed the animal studies conducted by Merrell, one cannot conclude from any of those studies that Bendectin is safe from a teratogenesis point of view. Moreover, as I further explain below, some of those studies indicate beyond a reasonable doubt

that Bendectin does cause birth defects and is, therefore, a clear cut or unequivocal teratogen.

6. When one refers to notebook 458T and 401T, which are the notebooks pertaining to study 63-28 on rabbits, one can easily note that the results in the notebooks are different from the results in the reporter's studies. I have conducted an audit of the notebooks and the studies in

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the same fashion that I have utilized and with the same methodology that I have utilized during my experience of doing such audits with the Federal Government. Having performed such audit, it is my view that the data collected in the notebooks clearly reflect that Bendectin was causing teratogenic effects in the rabbits being tested. Moreover, I have read memoranda from the company that also indicates that the principal scientist directing such studies at Merrell also concluded that at the very least additional studies were necessary. As far as I know, additional such studies were in fact not carried out at Merrell. Specifically, the animal studies on the rabbits in study 63-28 and in the notebooks, showed that there was an effect on the cartilage development in the ossification area such that it was not developing properly. This was a teratogenic effect on the skeletal system.

An examination of other studies done by Merrell with respect to doxylamine succinate continues to show increasing problems with the doxylamine succinate as concerns cell toxicity and teratogenicity and further shows that as the dosage increased, so did the teratogenic effects. This is another clear manifestation of teratogenicity.

7. From reviewing the additional studies, one finds that other abnormalities were discovered in studies done outside of the company. Namely, diaphragmatic hernias and other defects (Rolle); reduced weight in the fetuses

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(McClure); heart defects (Hendricks); and reduced ossification centers to a statistically significantly degree such that the chances were only one in one thousand that the drug Bendectin did not cause the defect (RTI). In the RTI study, the ossification centers, or areas that develop into bone, were significantly reduced.

Further, the animal studies that were performed by Merrell also had animals that had malformed limbs as well as other malformed bone structures.

8. It is standard practice to make extrapolations or render opinions as to the effect a drug would have on a human based upon animal data.

9. Thus, when having reviewed the data mentioned heretofore including the notebooks, studies done within the company and those done outside the company and utilizing my education, training and experience, there is no doubt whatsoever, certainly far beyond a reasonable doubt, and certainly within a reasonable degree of scientific certainty that Bendectin causes birth defects and is teratogenic in various animals. Therefore, I can state that based upon my education, training and experience within a reasonable degree of certainty, and in fact beyond any reasonable doubt, Bendectin and its component doxylamine succinate has the capacity to interfere with the normal development of cells in the human being and thus is a teratogen in the human being, at the normal therapeutic dose.**[10]**

10. I would like to point out that this opinion is further that the drug is a teratogen at the normal human therapeutic dose. Merrell repeatedly notes that animal studies involved dosages higher than those utilized in the human. There are many reasons for this. However, I would like to point out that this is the standard way of testing drugs in animals to determine their effect on humans. It is well known that individual humans have different levels of susceptibility to different substances such as drugs. So do lower animals. Rather than testing thousands and milllons of animals, the standard practice is to test at dosages that would be considered to be higher than the normal human dose and then extrapolate to the human. That is the generally and reasonably accepted methodology in the field.

11. I have further recently examined data provided by defendant that concerns the number of sales tablets sold in Canada over a period of time and an article by Iskenius-Froster, et al. which explores more than one in one-quarter million births in Canada during the period of time that Bendectin was and was not on the market in Canada. The Iskenius-Froster information details the rate of limb defects in those one in one quarter-million births. Having

performed the statistical analysis upon that data just mentioned in the same fashion that statistical analysis are generally performed in order to determine whether or not there is a statistical association between an agent and an

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effect such as a drug and a birth defect, one can see that there is in fact a statistically significant association that is highly significant between the sales of Bendectin in Canada and limb reduction defects. This is another piece of information that is useful which would generally and reasonably be relied upon to help determine whether or not a drug is a teratogen.

12. Based on the foregoing data concerning the Iskenius-Froster data and the data from the company concerning the sales of Bendectin, it is my opinion that within a reasonable degree of certainty that such information contributes to the knowledge that Bendectin does in fact cause birth defects in the human.

13. Moreover, the United States Government has identified in public documents that Bendectin is a developmental toxicant which is another term for teratogen. It is my strongly-held view that the animal studies do indicate clearly and unambiguously that Bendectin is a developmental toxicant.

14. In sum, based on my education, training, experience, review of the animal studies on Bendectin and its components including doxylamine succinate, it is my opinion within a reasonable degree of certainty that at the normal therapeutic dose Bendectin is a teratogen in numerous animal species as well as in the human, utilizing generally and reasonably accepted methodologies and that the Iskenius-

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Canada confirms this opinion.

/s/
Adrian Gross, D.V.M.

[notorization omitted]

UNITED STATES DISTRICT COURT
For the District of Columbia

NO. 83-3504

Sekou Ealy, et al.,

Plaintiffs,

v.

Richardson-Merrell, Inc.,

Defendant.

July 18, 1987
Courtroom 7
Washington, D.C.

The above-entitled matter came on for trial before the Honorable June L. Green at 9:55 a.m.

Reported by: Bonnie L. Gahagan

Dawn Copeland
Official Reporter
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Washington, D.C. 20001

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PROCEEDINGS

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(Jury not present.)

THE COURT: I see where I am a little bit early. Discussion off the record.)

(Jury present.)

THE COURT: Good morning, ladies and gentlemen.

THE CLERK: Civil Action Number 83-3504, Sekou Ealy, et al., versus Richardson-Merrell, Inc. For the plaintiffs, Barry Nace, John Sellinger; for the defendant, Mark Austrian and Patrick Coyne.

MR. NACE: Your Honor, at this time the plaintiff would call Dr. Adrian Gross.

Whereupon --

ADRIAN GROSS,

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. NACE:

Q. Good morning. Give us your full name, please?

A. My name is Adrian Gross, G R O S S.

Q. Doctor, what is your current place of

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employment?

A. I work in the United States Environmental Protection Agency.

Q. Have you previously worked for the FDA, Food and Drug Administration?

A. Yes, sir.

Q. Right at the beginning, are you appearing here on behalf of the Food and Drug Administration or the Environmental Protection Agency?

A. No, sir, I am not. I appear as a private citizen.

Q. Now, I said Dr. Gross. Are you a medical doctor?

A. No, I am a veterinarian, veterinarian medical.

Q. Let me ask you, doctor, where do you live?

A. I live in Maryland, Silver Spring, Maryland.

Q. Can you tell us where you went to college and where you had your post-college training?

A. Yes, sir. I matriculated in 1947 at the University of London, England, and then got my Bachelor's degree at the University of Manitoba in Canada in 1949. Then I took an additional year of postgraduate work there, and then went to veterinary

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school also in Canada, graduated in '54 with a D.V.M. degree, veterinary surgeon degree.

Q. What is the difference between D.V.M. and veterinary in surgery degree?

A. There is no basic difference. It just so happens that the one gets sort of a dual degree in Canada where the D.V.M. comes from the University of Toronto where the veterinary of college is veterinary of surgery, same courses.

Q. What year did you complete those two degrees?

A. In 1954.

Q. After you did that, what did you do?

A. I went into advanced pathology training and this was at the Ohio State University in Columbus. I got a Master's degree there in pathology and at the same time completed my work for -- the required work for --

Q. Let me pull this down for you, make it a little more comfortable.

A. Completed there in veterinary pathology and then I took a number of postgraduate courses in statistics and biometry at the Michigan State University.

Q. Let me stop you. What is biometry?

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A. Biometry is a branch of statistics that deals mostly with biological quantum, numbers and measurements arising in biological fields, as opposed to statistics in economic statistics.

MR. NACE: I may have pulled the microphone down too low.

THE COURT: I think he just let his voice drop.

THE WITNESS: I am sorry.

Q. Okay. Did you get a Master's degree?

A. Yes, from Ohio State.

Q. That was in what field?

A. In pathology.

Q. In pathology, is that human pathology, animal pathology or exactly what is it? Is it the same?

A. Pathology is the same. I took courses in both the medical school and in the veterinary school, carried out autopsy on animals, helped -- and also helped in autopsy with humans.

Pathology is a branch of medicine that deals with the nature of the disease process which is the same in animals and humans.

Q. What do you mean by that, that it is the same?

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A. Well, the basic mechanism by which disease arises is the same in all mammalian species. The humans have some of the same diseases as animals. Some diseases in humans don't have counterparts in animals and vice versa, but the basic fundamental process of disease is the same.

Q. Okay. Now, did you at any time have any military service?

A. Yes.

Q. Where was that?

A. That was in the British Army during the war, World War II, before your time. That was four years combat service in the British Army.

Q. Then have you been licensed to practice veterinary surgery, veterinary medicine?

A. Yes.

Q. Where have you been licensed?

A. I was licensed in '54 in Ontario and Ohio, Indiana, Michigan.

Q. Have you eventually been accredited by any organization?

A. No -- well, yes, I was accredited by -- I thought you meant something else, but I was accredited by the United States Department of Agriculture. I was accredited by examination.

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Q. What does that mean?

A. I suppose it means that I can carry out -- I have never done this actually, it is a long time ago, but what it meant, in my understanding, is that I could carry out all of the regulatory functions that the United States department of Agriculture expects of their veterinarians.

Q. Have you been employed as a pathologist?

A. Yes, sir.

Q. By whom have you been so employed?

A. Well, I started out with the United States Public Health Service in Cincinnati, the Occupational Health Service as it was called there when I was the research pathologist and then continued in a number of private research organizations such as the Arthur D. Little Company in Cambridge, Massachusetts, Microbiology Associates here in Bethesda and then became chief of pathology of the Food and Drug Administration in 1954 and then held some other titles for about 15 years in 1979.

Q. Let me ask you about your employment with the Food and Drug Administration.

A. Yes.

Q. When did you start there?

A. In 1964.

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Q. When you started there, what was your position?

A. Chief of pathology.

Q. As the chief of pathology with the FDA, what did your duties involve?

A. Well, I was chief of the pathology branch which meant that I supervised a number of professional pathologists, both human medical and veterinary medical who were engaged in examinations of tissues, doing autopsy on animals, so I was their supervisor.

Q. Okay.

A. Then, of course, we had a laboratory with a number of technicians to support such pathologists.

Q. Did the FDA do its own teratology testing?

A. Yes, and still does today, some of it, yes.

Q. Would you explain a little bit about that?

A. What a teratology test is?

Q. Well, what they do.

A. Well, they have a research program, both in house and

also they contract certain pathology studies at outside institutions, but what they do in-house is expose a variety of animals to test agents as we call them and food additives, drugs, so on, and we as pathologist have the responsibility of

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examining the animals for both defects and so on.

Q. After you served as the chief of pathology branch at the FDA, what did you do next at the FDA?

A. Next I became the deputy toxicological advisor working under Dr. Fitzhugh who was the toxicology advisor. I was his deputy, meaning his flunky. He gave me all sorts of jobs to help him with his jobs in the national and international agencies that he belonged to. Mostly I assisted him in that.

Q. I don't think we have had anybody explain what toxicology is yet. What is toxicology?

A. Toxicology is a medical discipline that deals with the adverse effects on health elicited by certain poisons. That is, the word toxic means poisonous. One can also look at toxicology as the same as -- or at least in the sense that the FDA did, they tested drugs, food additives, pesticides, cosmetics for safety, so toxic is the reverse of safety, so the experimental testing program is part of toxicology, trying to define what are the safe or the toxic properties of whatever they are testing.

There are a number of other stimuli or other agents that produce disease in animals or humans such as infectious organism, bacteria,

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viruses, on. This is not part of toxicology.

Toxicology is typically chemical agents, such as drugs, pesticides and so on.

Q. After you served there as a deputy toxicology advisor, what was your next position with the FDA?

A. Let me see. The title of that position is always a mouthful. I was assistant director for program coordination, I believe.

Q. What did that mean? What did you do?

A. Well, I was supposed to coordinate the research into safety of drugs.

Q. Coordinated it?

A. Yes, coordinated it.

Q. Then after that what was your position?

A. And then I became the associate director for preclinical investigations.

Q. What did you do in that position?

A. That was largely a job of -- I was, again, the chief of a branch and the associate director of a division of which the chief was Dr. Kelsey, and my job was at that time to go around the country and supervise all of the other scientists that did that, go around the country and audit studies in toxicology.

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Q. What did you do to the studies?

A. Audit.

Q. What is an audit?

A. An audit is a process where one looks into the reliability of reports submitted to the FDA.

Let me explain that under the food, drug and cosmetic act, the principal law that governs the mission of the FDA, the responsibility for testing the safety of drug products rests with what we call the regulated industries, meaning the manufacturers of the drug. They are the ones that are responsible for testing the drugs for safety.

Q. As opposed to the FDA?

A. Yes.

Q. Okay.

A. They do that themselves, and they are expected to do that, and then they submit reports to the FDA, and it is on the basis of such reports that the agency, A, approves or does not approve the drug for marketing, and B, if it approves if for marketing, it states what are the conditions for marketing, what labeling ought to be attached to a drug or what restrictions are to be imposed.

Q. Is that since the Kefauver Act?

A. Yes, 1960, Kefauver Act.

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So the FDA acts on the basis of such reports that it gets from the manufacturers or the regulated industries, but then there is always the question of how do we know such reports are reliable, and that is the function of the audit where one goes periodically on some of these reports, one goes into the laboratory which executed

the study, and the private industry, and one carries out an audit of the report against the actual observations that were made which are usually not submitted to the FDA.

Q. What is the difference between an audit and perhaps a review?

A. There are two different things. A review is carried out at headquarters by physicians, toxicologists, pharmacologists, chemists, they review the reports in order to assist the safety of the drug. That is the review function. They sit right here in Washington and review and evaluate the results, and an audit is an investigation, if you want, where the reliability of the report is investigated right at the site where it is executed.

Q. You did that?

A. I did that, yes.

Q. Would you actually look at the company's various notebooks?

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A. Yes, you look at the notebooks and see that all of the observations are properly reported, you check their facilities, is this the right sort of place to carry out studies like that, do they have the right equipment, are [their] laboratories the way they ought to be.

Q. Did you look at the animals themselves that may have been involved?

A. Right. Well, the animals we usually don't see because the audit is carried some time after the study, but we see other animals that are in progress, we look at their operation, we look at how their technicians work, you know, in the normal course of their duties, do they know what they are doing, what are their credentials, their training, their supervision, that sort of thing.

An audit is very much like an IRS audit. You are sending your income tax return, and if they have questions about this, you are supposed to explain what you did.

Q. Now, after you held this position, associate director preclinical investigations at the FDA, what was your next position?

A. Then I transferred to the Environmental Protection Agency where I became the chief of the

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toxicology branch which is a branch that does strictly what you term

review and evaluation in toxicology, so I was a supervisor of a large branch there with many, many toxicologists, and this went on for a year or so, and since 1980 and currently I am the senior science advisor.

Q. Well, let me ask you then what a senior science advisor has for duties?

A. That is easy. He gives advice.

Q. Besides give advice, in what areas?

A. Not in the stock market, in scientific areas, in my case toxicology, pathology, whatever. It is in the scientific areas.

Q. Have you done any publishing in the field of pathology and/or statistics?

A. Yes, a limited number. The material that we deal with certainly at the FDA and also in the EPA, the studies that we review and so on are largely confidential, so one is not at liberty to publish on one's work as a general rule.

Now, I have published one or two papers that deal mostly with methodology either in pathology or in statistics, but, as I say, both at the FDA and the EPA, what we work, publication is not one of the things one is expected to do.

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Q. Now, are you a member of the American Statistical Association?

A. Yes, I am.

Q. In work that you have done over the last -- well, with the FDA and the EPA, in what way are statistics used? How does that relate, I should ask, to biometry?

A. Well, it is really all biometry because we are dealing with data collected from biological systems, right?

I should say that statistical analysis, biometric analysis, statistical analysis of the results emanating from toxicology trials, typically have to be subjected to statistical analysis in order to reach an assessment, whatever we have tested, say a drug, is it or is it not safe, and it may be safe under certain conditions, but not safe under some other conditions, so this assessment of how safe an agent on test is based on the experimental data needs statistical analysis. Without that, one cannot conceive -- at least I can't conceive -- how a study such as this can be made. Sometime[s] a formal statistical analysis may not be necessary because the results are so clear-cut,

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either clear-cut negative or clear-cut very positive, either one is very safe or not very safe, so one may not need to go through the statistical analysis, but in actual fact, the process of evaluation always involves statistical analysis. It may not be a formal one because, as I say, the results may be obvious, but it is an implied function of assessing the safety of the chemical agent.

Q. Doctor, you told us a little about your pathology training. Have you had training in embryology?

A. Yes, when I was in school we had training in embryology, yes.

Q. Have you used that training in embryology throughout your career?

A. I have used it, but I wouldn't call myself primarily an embryologist, but I have used it, yes. In fact, one has to have an understanding of embryology to be a pathologist in the first place. Everything derives from an embryo or the tissues, and one has to know what is normal, what is abnormal in a developmental sense of an organism, but I wouldn't call myself an embryologist, but I have been trained in it.

Q. Are you familiar with the phrase

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teratology?

A. Yes, I am.

Q. What is teratology?

A. Teratology is sort of a term for -- it is a fairly new term. When I was in school there was no science of teratology, but now some people call themselves teratologists and there is a Journal of Teratology, there is a society, and members of it, I am not a member of a Teratology Society, but there are the people that deal with developmental types of defects, developmental toxicants or teratogens.

It is, as I say, a new term that I can't tell you exactly when it came into being, but sometime in the late '60s I would guess, perhaps early '60s, somewhere around that time, but teratology is, to my view, that branch of science that deals with abnormal development.

Q. What areas of science does it utilize?

A. I am sorry?

Q. What areas of science does it utilize?

A. What does it utilize?

Q. What teratology utilizes.

A. It utilizes certainly embryology, utilizes pathology, utilizes other parts of toxicology. Teratology test for a drug, let's say, is really

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just another kind of toxicity test. It is a test to determine the safety of this drug from a particular point of view, and that is, it focuses on the perinatal stage of development. In other words, it focuses on events very early in life, before life in the sense and shortly after birth.

Q. Let me ask you, have you yourself examined animals for birth defects?

A. Yes, sir.

Q. Could a teratologist do that, also, someone who calls himself a teratologist?

A. Yes, if he has training in this kind of pathology, yes.

Q. Have you analyzed data that has been used or collected for the purposes of determining whether or not a drug causes birth defects?

A. Yes.

Q. Has that been part of your function with the government in the past?

A. Yes.

Q. Do you consider yourself to be an animal teratologist?

A. No, not strictly.

Q. Why not? Why not?

A. Well, as I have said before, I am not

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regarded as such by the government as a teratologist, primarily a teratologist, although I have worked in this field, this is not my sole interest. My interest is largely in pathology, and pathology is broader than just teratology. Teratology, it seems to me, they restrict themselves to the areas, as I mentioned, limited to anomalies of development, early pathology changes. They don't go beyond that. I have never considered myself as a teratologist. As I said, I am not a member of the society, and that is the way I view myself

and others view myself.

Q. Are you familiar at all with how labeling takes place with drugs?

A. Yes.

Q. First of all, how have you become familiar with that?

A. Well, I put in 15 years with the FDA. If I wouldn't be familiar, I earned my money for nothing there.

Q. What kind of knowledge would you have with respect to labeling and safety?

A. Well, I would say most of what the Food and Drug Administration does in the area of drugs is related to labeling. As I was saying before, it is the responsibility of the agency to approve or

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disapprove of new drugs, and if they approve, they have to focus on whether the drug is properly labeled, so, the mission, this mission of the agency is the ultimate result of the efforts of practically all of the scientists that they have there that concern drugs, Bureau of Drugs, Bureau of Foods and so on. It is the ultimate responsibility and ultimate function of the agency and I would say most of the efforts and review of the scientists is aimed at that goal.

Q. Have you in the past given testimony in the field of adequate labeling?

A. Yes.

Q. Have your received any commendations or awards from the United States Government or agencies?

A. Yes, I have.

Q. Would you tell us about those, please?

A. Well, I have received personal commendations from the Commissioner of the Food and Drugs in 1970 some time, '75 or '76. I have received accommodations from Senator Kennedy, Ted Kennedy, who was the chairman of the Subcommittee on Health that same time, '76 or --

Q. Was that in response to a particular drug being investigated?

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A. Yes.

Q. We are not talking about Bendectin, so we are clear on

that?

A. No, it wasn't Bendectin. It was a series of drugs made by a single manufacturer at the time.

Q. Are you still called upon by congress and congressmen?

A. Yes, I was. As a matter of fact, just a couple of weeks ago they called me there to testify before them. They were looking into whether the approval for a drug was properly given by the FDA, and they asked me to testify in this regard. They sent me whole huge box full of material, documents, studies, reviews, and then they asked me to testify before them a few years ago.

My agency loans me out like a library book to other agencies who have problems. I am regarded in the agency as an international expert in the evaluation of safety of chemical agents, so other places periodically ask me.

The Food and Drug Administration asked me to help them after I was gone from their regular employment, so I spent time there testifying in trials for them and so on, and all of my testimony is always scientific. I testified as an expert in

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the area of science of the safety of drugs and other agents. I don't just give opinions. It is all based on review and evaluation of data.

Q. Doctor, have your performed an evaluation of various animal studies that have been done involving the drug Bendectin?

A. Yes, I have.

Q. In performing those reviews, have you utilized the methods and methodology that would generally and reasonably be accepted by those people dealing in the areas of evaluation of drugs for safety pruposes?

A. Yes.

MR. NACE: Your Honor, I would offer Dr. Gross as an expert in the field of pathology, animal pathology, toxicology, biometry and the evaluation of safety of chemical agents.

THE COURT: Questions.

MR. AUSTRIAN: Yes, I do, your Honor.

EXAMINATION ON THE VOIR DIRE

BY MR. AUSTRIAN:

Q. Good morning, Dr. Gross.

A. Good morning, Mr. Austrian.

Q. Now, as I understand it, you do not practice medicine or have a license to practice

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medicine; is that correct?

A. That is correct.

Q. Now, with the exception of a short period 20 years ago, you have never really practiced veterinary medicine; isn't that true?

A. That is true.

Q. Now, you are familiar with the concept of board certification?

A. Yes, I am.

Q. Board certification is available to individuals who practice in veterinary medicine that have additional training in certain areas; isn't that correct?

A. That is right.

Q. You had requested a training period for approximately 10 months to work in various institutions to prepare you for a certified examination; isn't that correct?

A. Well, it is partly correct, but not quite. From your question I get that this was the main purpose for my -- for that period of training from about 10 months in the early ' 70s, 1970, '71. The truth is that I went around, it was my sabbatical leave and I felt I ought to sort of recharge my batteries in pathology with the latest information,

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and I asked that I spend some time at a number of institutions in pathology, and I thought that with this I might also get -- prepare myself also for the examination for baord certification, but this was sort of frosting on the cake, I would say, but I eventually decided that I don't need it and I didn't want to be examined.

Q. You did not take the baord certification in veterinary pathology?

A. No, I didn't.

Q. You were not certified in the field of veterinary pathology; is that correct?

A. That is correct.

Q. You are not board-certified in any field; is that correct?

A. That is correct.

Q. You do not have any advanced degrees from a recognized university in either statistics or biostatistics; isn't that correct?

A. That is correct.

Q. You do not consider yourself to be a statistician, do you, Dr. Gross?

A. That is correct.

Q. As I understand it, you graduated from the University of Manitoba, 1949?

* * *

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Drug Administration; isn't that correct?

A. From '64 to '68, yes, correct.

Q. Now, at that time you did not have principal responsibility for evaluation of teratology data, did you, doctor?

A. That is correct.

Q. The evaluation of teratology data was done be reviewers at the Food and Drug Administration who are mostly pharmacologists and toxicologists; isn't that correct?

A. That is correct.

Q. You did not do any animal teratology testing in that position, did you, doctor?

A. Well, as I explained earlier, I participated in such trials by doing the pathology examination of the newborn which is the critical aspect. Now, I did not direct such studies, I didn't originate them, I didn't -- this was my responsibility, but in fact, I participated in such tests.

Q. Let me ask again: You did not yourself, you yourself, have the responsibility, and did not do an animal teratology test while you were chief of pathology; isn't that true?

A. I don't know what you mean by you did, I

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did such tests.

THE COURT: What kind of tests did you do, doctor?

THE WITNESS: Well, your Honor, the animals are put on tests by some scientist, if he decides what tests should be done and the animals are to be dosed to such an agent for such amounts, and then one waits to see what happens. These are usually female

animals that are pregnant and that give births to litters of pups and then they are examined for any birth defects.

Now, I participated in precisely that, examining the animals. This is what I did, and I have explained this.

Now, the actual putting --

THE COURT: These were what, newborn baby animals?

THE WITNESS: Yes, ma'am, yes, these were animals. These are experimental studies.

THE COURT: What kind of animals were they?

THE WITNESS: Well, there were rabbits, rats, we used -- I am trying to think of the name of this animal. It just escapes me now. It is another species of animals that we used and the name just escapes me now. Gerbils, some monkeys I have done,

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examination of newborn monkeys, and that is what I did.

MR. AUSTRIAN: May I continue?

THE COURT: Yes.

MR. AUSTRIAN: Thank you, your Honor.

BY MR. AUSTRIAN:

Q. Now, from 1968 to '69 I believe you testified you were deputy toxicology advisor; is that correct?

A. Yes, sir.

Q. You did not do any teratology testing in that position, did you?

A. No.

Q. 1970 to '74 you were assistant director for program; is that correct?

A. Yes.

Q. Your responsibility in that position was mostly coordinate the research activity of the Bureau of Drugs?

A. That is right.

Q. At that time you did not do research in teratology or evaluation of teratology data in that position; isn't that correct?

A. That is correct.

Q. You have never at any time been the one

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who has actually selected or determined what doses were to be given in an animal teratology study; isn't that correct?

A. Absolutely correct.

Q. In fact, you have never at any time been responsible for the design or the execution or the initiation or supervising of any animal teratology studies; isn't that correct?

A. That is correct, yes.

Q. From 1975 to 1979 you were associate director for preclinical investigation at the Food and Drug Administration, correct?

A. Correct.

Q. Your investigation was limited to whether the report was properly done and reliable, true?

A. Yes.

Q. However, the primary responsibility for evaluating an animal teratology study to see if it raised a safety concern was that of another division of the Food and Drug Administration, the reviewing division; isn't that correct?

A. Sir, there were many reviewing divisions, there still are today, in the Bureau of Drugs. Each division reviews drugs in a particular area. There is a review division that deals with cardiovascular

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drug, another one with infectious agents, so there are many reviews.

In my capacity as pathologist, I was frequently asked to help the primary reviewers -- I was not the primary reviewer, I will grant you that.

MR. AUSTRIAN: Your Honor, I believe my question was very specific. I asked him isn't it the fact that the primary responsibility for evaluating animal teratology studies to see if it raised a safety concern was that of another division at the Food and Drug Administration, the reviewing division.

Q. Isn't that correct, doctor?

A. Sir, there are many reviewing divisions, and I am saying to you, again, and you are right, that is their primary responsibilities.

Q. Thank you, doctor.

A. However --

MR. AUSTRIAN: Your Honor.

MR. NACE: Let him explain.

THE COURT: Did you serve in the other branches or

with them ever?

THE WITNESS: I did not serve in a reviewing division, but I was called upon in a consulting capacity to help in the evaluation of

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drugs from a safety point of view in many different aspects, including teratology.

MR. AUSTRIAN: Continue? Thank you.

BY MR. AUSTRIAN:

Q. In 1979 you went to the EPA as senior science advisor; isn't that correct?

A. No, I believe I testified that I went there as the chief of toxicology.

Q. I am sorry. That deals mainly -- the EPA deals mainly with pesticides and not drugs; isn't that correct?

A. Yes.

Q. Now, you have never actually done, I believe we have established, an animal teratology study, true?

A. I have never initiated, supervised or originated a teratology study.

Q. Or carried one out?

A. Well, I have carried out parts of it.

Q. You never carried out a whole teratology study?

A. Well, I don't think anyone does. I carried out the pathology functions.

Q. All right. Now, you are not generally familiar with substances which are teratogenic in

[681]

animals, are you?

A. No, I am not.

Q. That is because you are not an animal teratologist, correct?

A. That could be, yes.

Q. There are people who actually do teratology studies and are known as animal teratologists; isn't that correct?

A. Yes.

Q. You are not a specialist in animal teratology, are you, doctor?

A. No, I am not.

Q. While you were at EPA, there was nothing that prevented

you from publishing articles of scientific interest, isn't that true?

A. As I was saying before, the work consists there of review and evaluation of the safety of pesticides in my outfit, and I also explained that most of these data are confidential. You cannot publish them. Publication is not encouraged there. Now, does that answer your question?

Q. No. Was there any legal requirement that if you were doing studies or had an area of scientific interest that prevented you from publishing?

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A. But that is not my function in the EPA to do research and develop new methods. That is not what I am doing.

Q. So the answer to my question is no?

A. Say the question again.

Q. There was no legal requirement while you were in the government from publishing articles of general scientific interest; isn't that correct?

A. If that were my job, that would be true. As it happens, it isn't my job.

Q. You do not have any teaching appointments at any academic institutions, do you, doctor?

A. That is correct.

Q. You have never had any such appointments; isn't that true?

A. Yes, that is correct.

Q. You have never published any articles in the scientific literature dealing specifically with the subject of teratology or birth defects, isn't that correct?

A. That is true.

Q. You are not a member of any professional organizations dealing with the study of birth defects?

A. That is right.

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Q. You do not consider yourself to be an expert on FDA regulatory requirements; isn't that correct?

A. Well, I don't know what an expert is in FDA regulatory requirements, so I can't answer that question. I just don't know that there are such people. I would say that I am familiar with the FDA regulatory requirements.

Q. I am sorry?

A. I am familiar with the regulatory requirements. I don't consider myself an expert, but I don't know who is an expert.

Q. Whether somebody else may be, you don't consider yourself an expert in FDA regulatory requirements; isn't that correct?

A. I would say that I am familiar. I don't know what the word is -- I don't recognize this as a field of expertise. I certainly don't view myself as one, and I don't know anyone else who is an expert in this area. There is no such recognized expertise, as far as I am concerned. I am familiar with the regulatory requirements. I will let it go at that.

Q. You did not have any responsibility prior to 1976, though, with any kind of regulatory

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supervision or reporting requirements under the FDA acts; isn't that correct?

A. No, that wouldn't be correct at all. I know what the regulated industry is supposed to be doing and I knew what the FDA was supposed to be doing.

Q. That is not my question. Prior to 1976 you did not have any responsibilities in connection with the reporting requirements while you were at the FDA; isn't that correct?

A. I am sorry, Mr. Austrian, I lost the question, if you don't mind.

Q. Yes. You were aware that there were reporting requirements for submission of data to the FDA prior to 1976; isn't that correct?

A. Yes, that is correct.

Q. None of the things that you were doing at the Food and Drug Administration prior to 1976 involved supervising or overseeing whether companies had complied with the reporting requirements; isn't that correct?

A. Oh, I see what you are saying. Yes, that would be correct.

Q. Now, you are not a pharmacologist, are you, doctor?

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A. I am certainly not a pharmacologist. I work in the field

of toxicology.

Q. And you are not an epidemiologist, are you?

A. No.

Q. And you had nothing to do with Bendectin until 1986; isn't that correct?

A. That is correct.

Q. And the way you got involved with Bendectin is that you received materials from attorneys; isn't that correct?

A. That is correct.

Q. While you were either at the EPA or FDA, you had nothing to do with Bendectin; isn't that correct?

A. That is correct.

MR. AUSTRIAN: Nothing further on voir dire, your Honor.

THE COURT: Approach the bench.

(At the bench.)

THE COURT: What are you offering him as an expert in?

MR. NACE: Toxicology, pathology, review of animal studies and how they are done by the company, auditing and the safety of chemicals and drugs and biostatistics.

* * *

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A. Your question is, sir, how does one draw conclusions from observational data?

Q. Yes.

A. Well --

THE COURT: How do you in particular?

THE WITNESS: Well, I believe I do it the same way everybody else does.

A. That is subject the data to a scientific sort of judgment, what we have here. I mean is this agent safe or dangerous.

As I was saying, there are a variety of techniques one uses in this process, statistical techniques mostly, and one reaches a --

Q. I am sorry, could you repeat what you said?

A. The data have to be analyzed statistically. Let me explain so that it is very clear. Suppose one carries out a test, and typically

teratogenicity tests, there are a number of other safety tests, toxicology tests, they are done at four levels. One is a group of animals that receives nothing, nothing in the way of the agent on test, just his own food, diet and so on. These are called the control animals. Then there are three other groups. One receives a relatively low dose of the agent on test and then there is a medium dose and then there is a

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high dose. We have four groups, control, low, medium and high.

Birth anomalies, let's say, could be present in all of these groups. They could be present in the control group as part of a general background or toxic, noxious agents that are in the environment, and then at the next dose there may be some and there may be some at the medium dose and there may be some at the high dose. Well, how does one reach a conclusion, evaluation conclusion did the agent on test cause an increase in the incidence of birth defects or congenital anomalies?

In order to answer that question, one must carry our statistical analysis of the results. Without that it is inconceivable to me how one can reach any conclusion. Not just on birth defects, but on anything else. Does the agent damage the eye? Does the agent produce neuro-type effects? This is common to the whole field of toxicology.

Q. What do you look at to make those determinations?

A. Well, one has to compare the results in a prescribed scientific manner to answer the question are these results that we see here just results that one could expect from random occurrences, or are

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they due to the agent on test, all right? That is the crucial question here, and in order to answer that question, one has to carry out the statistical analysis of the results.

As I said before, without this it is inconceivable to me how one can answer the question is this agent safe or not safe.

Q. Does that kind of analysis answer the question of cause and effect?

A. Yes, sir, absolutely, and without this analysis, this question cannot be answered.

Q. Is this what you have been doing in the past?

A. I have been doing this for -- yes, for at least a couple of decades.

Q. A couple of decades?

A. Yes, sir.

MR. NACE: May I proceed, your Honor?

THE COURT: Yes.

MR. AUSTRIAN: May I voir dire?

THE COURT: Yes, all right.

EXAMINATION ON THE VOIR DIRE

BY MR. AUSTRIAN:

Q. Doctor, you are not generally familiar with the literature in animal teratology; isn't that

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correct, the published literature?

A. That is correct, I don't review that as a matter of routine.

Q. The statistical technique that you use, this statistical technique that you use, I am talking about the work you actually do at the FDA and EPA, you do not use that statistical technique in evaluating animal teratology studies; isn't that correct?

A. I wouldn't say that is necessarily correct because I may in fact have used that, and I look for whether the sponsors, the manufacturers have used that.

Q. I am talking animal teratology tests, doctor?

A. What about it?

Q. Let me ask it a different way.

The statistical technique you use, isn't it a fact that you have never seen anyone in the published scientific literature dealing with birth defects ever use it?

THE COURT: Ever use what? I am sorry.

Q. I will rephrase it. Isn't it a fact that the statistical technique that you use has never been used in any animal teratology study that has

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been published in a peer-review journal?

A. I can't answer the question to you, Mr. Austrian, because I do not make it a routine practice of mine to review what is

published, but I can tell you this: In teratology studies that come to the attention of the Environmental Protection Agency when I was the chief of toxicology and I supervised the people that reach these kind of evaluations, they are looking for these types of analysis that I am talking about, statistical analysis, because without such statistical analysis, it is impossible to reach a conclusion on the safety of the agents on test, and the answer to your question is one does expect in the way of such studies that come to my attention or come to the attention of the government. That is what we are looking for. If there are no such analysis, we do these analyses ourselves.

Q. Let me ask the question again. You use a statistical technique, not generally, but you have a specific statistical technique called a linear --

A. I am sorry?

Q. The statistical technique that you use is a linear regression analysis; isn't that right?

A. In parts of the data I use linear

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regression analysis. Other parts are different.

Q. I am talking about your statistical analysis, the way you use it in analyzing these tests?

A. I have used a variety of statistical analyses on the work I have done on Bendectin.

Q. I am going to cut through.

Isn't it a fact that you have testified in the past in response to this question on the technique that you have used that you have given these charts where you have -- I think you called it a computer program, where you come up with these linear regression lines, "Answer, Yes, sir."

"Question: You are not aware of any teratology study that has ever been published that uses the specific technique that you use; isn't that true?["]

"Answer: I am not aware of any, but then I don't know what weight you can put in that because I read very little."

Isn't it a fact that you were asked those questions and gave that answer?

A. I gave you the same answer today, Mr. Austrian.

MR. AUSTRIAN: Thank you. May we approach,

* * *

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dictionary with medical terms in it?

A. Yes, it is probably the best known.

Q. Does that have the phrase teratology in it?

A. Oh, you mean the dictionary?

Q. Right there.

A. Oh, I see. Teratology.

Q. How is it defined?

A. That division of embryology and pathology which deals with abnormal development and congenital malformations.

Q. Is that the area that you have worked in?

A. Yes, sir.

Q. Let me ask you then, also, doctor, what is a developmental toxicant?

A. Developmental toxicant is a synonym for a teratogen, meaning an agent that is toxicant to an organism around its birth, in the period of time surrounding its birth, shortly before and shortly after birth.

Q. Doctor, based upon your experience and your education, what are the signs of a teratogen in an animal study?

A. Yes, well, I will give you that definition as it was given in the textbook written by Fraser and Wilson, Wilson and Fraser I should say identify

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a teratogen.

Q. What is it?

A. I don't know if I recall it word for word, but basically they say a teratogen is any agent that can elicit or can produce one or any of the following: Birth defects in the accepted sense, a congenital anomaly or birth defect is something that one sees. It is an anomaly of structure or anatomy. That is one effect of a teratogen, or it can be death of the embryo or fetus. That is really the ultimate insult, you might say. It can also retard growth, retardation of growth is another manifestation of a teratogen, or it can manifest itself in an anomaly of function.

Q. What does that mean?

A. As opposed to -- well, it is the way an organism works

rather than the way an organism looks.

Q. Doctor, let me show you, first of all, what has been marked as Plaintiff's Exhibit 10, project report 6301. Have you reviewed that previously?

A. Yes, I have seen this, yes.

Q. In reviewing it, have you reviewed it in the same fashion and the same manner which you would generally review other laboratory data and reports?

* * *

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MR. AUSTRIAN: When people have experience with human beings, and this witness has no experience with human beings.

THE COURT: I think he has probably never been asked to make that determination in his job or the jobs that he has had. I think he has always been asked to see whether the tests were made in accordance with the usual standards for making the tests, and I doubt that he has ever been called upon to make this decision because I think that it has been undoubtedly made by somebody else.

MR. NACE: Can I explore that?

THE COURT: Yes.

(In open court.)

BY MR. NACE:

Q. Doctor, when these particular studies are done on animals, first of all, why are they being done?

A. Why are they being done?

Q. Yes.

A. I will tell you one reason they are not being done for, we are not interested in whether Bendectin is safe to rats, rabbits and mice. That is clear. They are done for only one purpose, to establish the safety of these products for humans.

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Q. As a pathologist who has been with the FDA and the EPA, have you had occasion to participate in decisions as to the meaning of the kind of data that we have been talking about as applies to humans?

A. Yes, of course. That is what we are doing all the time.

I mean the object of doing these studies is to estimate, to evaluate, to assess whether these agents are going to be safe for humans. They have no other purpose. They are not done for the benefit of the animals.

Q. Can one make extrapolations then or conclusions from looking at the animal data to decide what would happen in the human?

A. Yes, sir, that is their purpose.

Q. How do you do that?

A. Extrapolate the safety to humans.

MR. AUSTRIAN: Objection.

THE COURT: Have you ever been called upon to make that determination in any of the positions that you have had? Is it somebody else who determines it from the data that you have?

THE WITNESS: There is no one else either at the FDA or the EPA that makes such assessment other than the people who review those data. Toxicologists such as myself make it, pathologists

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and so on. There is -- I don't know if I am explaining this correctly.

First of all, these studies that were done, say, by Merrell are submitted to the Food and Drug Administration to present their view, right, this is the documentation of their view that the drug that they make is safe for humans, not for rats, rabbits and so on. That is the purpose that they are doing such tests. Bendectin is not sold to animals. The reviewers in the FDA, again, toxicologists, pathologists such as myself, they all have the human animal as a point of reference and concern. That is why we are working there.

THE COURT: When all of the information is put together, the person in which position makes the final decision as to whether or not it is safe for human being or unsafe?

THE WITNESS: I cannot answer what person, but I can--

THE COURT: What position?

THE WITNESS: What position or rather what discipline goes to that.

THE COURT: No, the final analysis. Who finally says that is okay or this is not okay. To whom does that fall?

* * *

8. Excerpts of testimony of James W. Newberne, D.V.M., in *Ealy v. Richardson-Merrell, Inc.* (Ex. 27 to Pltfs.' Opp. to Summ. Judg.), filed Aug. 22, 1989

UNITED STATES DISTRICT COURT
For the District of Columbia

NO. 83-3504

Sekou Ealy, et al.,

Plaintiffs,

v.

Richardson-Merrell, Inc.,

Defendants.

June 30, 1987
Courtroom 7
Washington, D.C.

The above-entitled matter came on for trial before the Honorable June L. Green at 10:05 a.m.

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[2506]

THE COURT: All set

MR. AUSTRIAN: Thank you your honor. At this time the defendant would call Dr. James Newbern to the stand.

JAMES W. NEWBERNE,
a witness, called for examination, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION
BY MR. AUSTRIAN:

Q. Good morning Dr. Newberne.

A. Good morning.

Q. Dr. Newberne, are you presently employed by Merrell Dow Pharmaceuticals?

A. Yes, sir.

Q. What is your present position?

A. My present position is vice-president of drug safety assessment.

Q. Are you a veterinarian?

A. Yes, sir.

Q. Are you a pathologist, veterinary pathologist?

A. Yes, sir.

Q. Can you tell me whether during the period

* * *

[2678]

makeup of the organism is important. That is essentially what he said, and that it does react to the environment and to the events around it.

Q. What he is saying is that in an animal that different animals may have different degrees of susceptibility depending on their makeup, isn't that right?

A. That is true.

Q. Of course, that also applies to man, doesn't it?

A. It is my understanding that it does, yes.

Q. Okay. Now, doctor, he goes on and gives on the next page the second principle, where he says:

"Susceptibility to teratogenic agents varies with the developmental stage at the time of exposure."

I read that right, didn't I?

A. Yes, sir.

Q. What he means by that is whether or not the animal is going to be susceptible to being affected by the teratogenic agent depends on whether or not the agent is present at the time that a portion of the body is developing; isn't that right?

A. That is my understanding.

Q. Timing is important?

[2679]

A. Timing, yes.

Q. Okay.

Then if we go back to page 54, it says number 3, "Teratogenic agents act in specific ways (mechanisms) on developing cells and tissues to initiate abnormal embryogenesis (pathogenesis)."

Did I read that right?

A. Yes.

Q. What that means is that the teratogens do something to affect the way the cells are developing to cause it, abnormal development; is that basically right?

A. In the context of this entire chapter, as I understand it, your comments are correct. What Dr. Wilson is referring to here is the developing cells and tissues in the complete animal.

Q. Sure. Again, both number 2 and I referred to and number 3, the timing question, and the mechanisms, that applies to humans as well as to the other animal species; isn't that right?

A. I think that is correct.

Q. We are all animals of some sort; that is right?

A. That is right.

Q. Okay.

* * *

[2698]

animals at a human dose, you would have to test thousands of animals in order to find out if there is a relationship between the drug and the teratogenic effect?

A. Early on in consideration of a study I don't give any consideration myself and I think this is true among most teratologists that one should even consider the human dose in that context. One should first consider what high doses, low doses or any other kind of dose is doing to that particular animal, and from the data derived from that animal, make a judgment of predictive value in human beings.

Q. To you, sir, last -- I believe it was April or May of 1986. The question is at page 61.

"Doctor, it is true that high doses are used in animal tests purposely, there is a purpose in use for selecting high doses, correct?

"Answer: That is a school of thought.

"Question: Do you agree with that school of thought?

"Answer: In a general sense I agree with it.

"Question: If we tested drugs at the human dose, you would have to test hundreds or thousands of animals, correct?

* * *

9. Affidavit of Shanna Helen Swan, Ph.D and curriculum vitae (Dock. No. 187), and excerpts of testimony in *Ealy v. Richardson-Merrell, Inc.* (Ex. 12 to Pltfs.' Opp. to Summ. Judg.), filed Aug. 22, 1989, and Sept. 28, 1989

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UNITED STATES DISTRICT COURT
For the Southern District of California

NO. 84-2013-G(I)

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardian[s] Ad Litem for JASON DAUBERT, a Minor,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50 Inclusive,
Defendants.

NO. 84-2929-G(I)

MICHAEL SCHULLER, ANITA DE YOUNG, and ANITA DE YOUNG as Guardian ad Litem for ERIC SCHULLER,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50., Inclusive
Defendants.

AFFIDAVIT OF SHANNA HELEN SWAN

1. My name is Shanna Helen Swan.

2. I am an epidemiologist and biostatistician. I have a PhD in statistics. I practice in the field of reproductive epidemiology full time for the State of California. A copy of my curriculum vitae is attached hereto.

I was graduated from the City College of New York with my major in mathematics. I received a masters in biostatistics from Columbia University and then receive a PhD in statistics from the University of California at Berkeley. I have taught at the University of California. My teaching has involved the areas of statistics, biostatistics, epidemiology, and mathematics. Mathematics is the foundation for each of biostatistics and epidemiology. It is necessary that one have an understanding of statistics in order to teach epidemiology and to understand the meaning of epidemiology findings. I hold a [lecturer] position in epidemiology in the School of Public Health at the University [of] California at Berk[e]ley.

My current title is Chief of the Reproductive and Epidemiological Program of the Epidemiological Study Section of the California Department of Health and Services. My duties include the study of causes of adverse reproductive outcomes.

I have served as a consultant to the World Health Organization, to the Food and Drug Administration, and to the

National Institutes of Health. I belong to numerous professional societies that deal with epidemiology and statistics including the American College of Epidemiology, the American Statistical Association, the Society for Epidemiological Research, the Institute of Mathematics Statistics, the Biometrics Society and the American Public Health Association. I am a member of the Phi Beta Kappa Society. I have served as a reviewer for the epidemiological, statistical and medical publications including the American Journal of Epidemiology, American Journal of Public Health, The American Statistical Association, the Journal of the American Medical Association and others. I have served on study sections for the National Institutes of Health. I have published approximately 25 to 30 times in the field of epidemiology, biostatistics and statistics including an abstract with respect of Bendectin. I have co-authored numerous government documents from the state of California including those pertaining to pregnancy and pregnancy outcomes.

3. In my position with the state of California I am called upon to help determine causes of adverse pregnancy outcomes including birth defects where we utilize primary and secondary data. The type of data that I utilize and will be discussing below is all of the type of data that is generally and reasonably relied upon by epidemiologists to help determine whether o[r] not there is a statistical association

[4]

between a drug, such as Bendectin, and a class of birth defects such as limb reductions.

4. I have reviewed, to the best of my knowledge, all the epidemiological literature pertaining to Bendectin.

5. Because of my position, experience, education, and training I am aware that in vitro studies, animal studies and the pharmacology of drugs are all important along with epidemiology studies in determining whether or not there is a cause and effect relationship between drug and a birth defect. Decisions concerning whether or not there is such a cause and effect relationship between a drug and birth defects are not made solely on epidemiological data when one is concerned about teratogenicity issues. One would not rely solely on epidemiological studies that failed to show a statistical association at the 95% confidence level between a substance and a defect to determine that the substance does not cause the defect.

6. In order to understand epidemiology studies one must understand that the results can be positive, negative, or inconclusive. An inconclusive study is one that does reach traditional levels of statistical significance but does not have the statistical power to rule out appreciable relative risks. In other words, the data could be consistent both with no effect and with an effect that one was worried about such as a doubling of risks. A positive study at a traditional level of statistical significance, e.g. 5% would enable one to

[5]

conclude with 95% certainty that there is statistical association between a cause and effect or between a drug and a birth defect. In analyzing the validity of an epidemiological study one must analyze not only the chance of the error of a false positive, e.g.5%, but also the "power" of the study, the chance of detecting an association if it exists. A confidence interval indicates that the true association level is somewhere in the range between the lower limit an the higher limit of probability. The less sure one wants to be about the finding, the narrower is this range. For example for a 90% confidence level, the range would be narrower than for a 95% level and even narrower for an 85% confidence level and so on. It is erroneous to conclude that merely because a confidence interval includes the number 1.0 that one can conclude from such data that there is no statistical association or no causation. One must look at all the studies and evaluate their quality and power using one's education, training, and experience and generally accepted methodology to come to an opinion as to whether or not the data shows an association.

7. It is not usual epidemiological practice for the author of a study to "conclude" that the data does or does not "prove" a cause and effect relationship. That is neither the nature nor purpose of such a study or studies. The purpose of such data collection is to add another body of data to other scientific data such as pharmacological data, animal studies

[6]

data, and in vitro data to enable one to reach an opinion concerning the effect of the agent.

8. For example, in reviewing the various epidemiological studies on Bendectin, the most powerful study, i.e. "Jick", only has

approximately a 17.6% chance of finding a doubling of the rate of defects. The other studies are even less apt to find even a doubling. Even if one were to put all the studies together that involve the limbs, there would still be less than a 50% chance of finding a doubling of increased limb defects and only a minuscule chance of finding 50% increase or a 20% increase. In analyzing the various epidemiology studies, one quickly can see that the studies either have insufficient numbers, inappropriate control groups, inappropriate pooling of malformations, misclassification of exposure, or confounders.

9. It is not accepted epidemiological practice to rely solely on epidemiological studies that provide relative risks with confidence intervals which include 1.0 and conclude that Bendectin does not cause birth defects. Such studies may in fact provide data consistent with a greatly increased risk.

10. Having reviewed the epidemiological studies including, but not limited to Heinonen, Jick, Aselton, Morelock, Cordero, Eskenazi, McCredie, and based upon generally accepted epidemiological techniques and utilizing my education, training and experience it is my opinion that one cannot conclude that there is in fact no statistical

[7]

association between Bendectin an limb reduction defects. More specifically one cannot draw a conclusion from those studies that Bendectin does not cause limb reduction defects.

11. Because limb defects are a rare occurrence, occurring less than one per one thousand live births, many thousands of births would be necessary in a controlled study to reveal even a 100% increase. The chances of finding a smaller increase such as a 10% or 20% would therefore be minuscule. That is one reason why an epidemiologist would not rely only on epidemiology studies in the face of other scientific data to suggest that a drug, such as Bendectin, does not cause birth defects. On the contrary, the prudent epidemiologist would be concerned about the public safety and when there is data consistent with increased risks, as with Bendectin, conclude that it is more probable than not that Bendectin is associated with birth defects.

12. Rather, considering the foregoing studies, within a reasonable degree of certainty, based upon my education, training

and experience, it is my opinion that considering all available data that is provided in animal, in vitro and epidemiological studies, including the relative risks, the confidence limits and also the power of the studies, that it is more likely than not that Bendectin is, in fact, associated with limb reduction defects. in reaching that opinion, I have used the methodology that is generally and reasonably relied upon by epidemiologists to analyze, study and interpret data

[8]

that has been collected, published and unpublished in trying to draw opinions concerning whether or not there is a cause and effect relationship between a drug and a birth defect.

13. I have previously given testimony in cases involving Bendectin and subsequently learned that the defendant in these cases has taken bits and pieces of my testimony out of context. However, so there be no question, it is my opinion within a reasonable degree of certainty, based on all of the available data, the Bendectin is associated with birth defects, including limb defects.

/s/
Shanna Helen Swan

Sworn to and subscribed in my presence on this 27th day of September 1989.
State of California
County of Alameda

/s/
Notary Public

CURRICULUM VITAE

Shanna Helen Swan
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Berkeley, California 94707
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EDUCATION

1963 — DOCTOR OF PHILOSOPHY
Department of Statistics
University of California, Berkeley

Dissertation Topic:
Limiting Distributions of Random Sums of Independent Random Variables [see publication (1)]

1960 — MASTER OF SCIENCE
Department of Biostatistics,
Columbia University, New York
Regents Teaching Fellow

1958 — BACHELOR OF SCIENCE (Mathematics; Magna Cum Laude) City College of New York, New York Honors in Logic (Ward Medal)

NONACADEMIC EXPERIENCE

1981 to present — CHIEF
Health Assessment and Surveillance Unit
Epidemiologic Studies and Surveillance Section
California Department of Health Services-
Berkeley, California

Directing and carrying out research on reproductive effects of toxic substances, providing consultation staff on the design and analysis of epidemiologic projects, supervision of unit staff.

1969 to 1978 — SENIOR BIOSTATISTICIAN
Contraceptive Drug Study Kaiser Permanente
Medical Center Walnut Creek, California

Directed and carried out research on noncontraceptive side effects of oral contraceptives." Designed and supervised study of cervical carcinoma, oral contraceptive use and sexual behavior, developed grant proposal for study of vasectomy and cervical carcinoma [see publications (11) through (22)].

1972 — CONSULTANT IN CONTRACEPTIVE RESEARCH
World Health Organization
Bangkok, Thailand

1971 — RESEARCH ASSOCIATE
Berkeley Pediatric Group
Berkeley, California

Designed and analyzed study on tetracyclines and tooth color in children [see publication (10)].

1964 to 1967 — RESEARCH SEISMOLOGIST
Department of Seismology
University of California, Berkeley

Analyzed seismological data on travel times of P waves; designed and supervised study on reliability of reading of seismograms collaborated with international committee on revision of travel time standard tables [see publications (2) through (9)]

ACADEMIC EXPERIENCE

1980 to present — LECTURER IN BIOSTATISTICS AND EPIDEMIOLOGY
School of Public Health
University of California, Berkeley

Responsibilities include: teaching biostatistical and epidemiologic methods, supervision of graduate research.

1979 to 1981 — DIRECTOR
Graduate Training Program in Biostatistics and Epidemiology
School of Public Health
University of California, Berkeley

Responsibilities included: supervision of graduate research projects, supervision of field placements, maintenance of data archives, lecturing in biostatistics and epidemiology.

1978 to 1979 — VISITING ASSOCIATE PROFESSOR
Department of Statistics. Chairman: Peter Bickel
University of California, Berkeley

Responsibilities included: teaching both introductory probability and statistics, supervision of Teaching Assistants and Readers.

1973 to 1979 — ASSOCIATE PROFESSOR
Department of Mathematics. Chairman: Robert Johnson
State University of Sonoma, Rohnert Park, California
Responsibilities included: teaching introductory and advanced probability and statistics, development of interdisciplinary courses; supervision of Masters students.

1968 to 1969 — LECTURER
Department of Biostatistics. Chairman: Jacob Yerushalmy
University of California, Berkeley

Responsibilities included: teaching of introductory biostatistics.

1967 to 1968 — LECTURER
Department of Statistics. Chairman: Joseph Yahav
University of Tel Aviv, Israel

Responsibilities included: teaching applied statistics, supervisor of student research.

1963 to 1964 — ASSISTANT PROFESSOR
Department of Statistics. Chairman: Lucient le Cam
University of California

Responsibilities included: teaching introductory probability and statistics[.]

1960 to 1961 LECTURER
Department of Statistics. Chairman: Anders Hald
University of Copenhagen, Copenhagen, Denmark

Responsibilities included: teaching introductory and graduate seminar in probability theory.

PROFESSIONAL SOCIETIES

Phi Beta Kappa
American Public Health Association
Biometric Society
Institute of Mathematical Statistics
Society for Epidemiologic Research
American Statistical Association
American College of Epidemiology

REVIEWER

Journal of the American Statistical Association
American Journal of Epidemiology
Journal of the American Public Health Association
Journal of the American Medical Association

COMMITTEE MEMBER

American Statistisal Association Committee on Law and Justic Statistics

STUDIES SECTION MEMBER

Health Services Developmental Grants Review Subcommittee, National Center for Health Services Research (1986-1988).

SPECIAL STUDIES SECTION MEMBER

Contraceptive Evaluation Branch, National Institutes of Health,
Child Health and Development Branch, National Institutes of Health,
Oral Contraceptive Review, FDA

PUBLICATIONS

(1) Freedman, H.*: Limiting distributions of random sums of independent random variables. Z. Wahrscheinlichkeitstheorie 3:7-18, 1964.
(2) Freedman, H.*: The "little variable factor," a statistical discussion of the reading of seismograms. Bulletin of the Seismological Society of America (B.S.S.A.) 65 (2): 593-604, 1966.
(3) Freedman, H.*: A statistical discussion of Pn residuals from explosions. B.S.S.A. 65(3): 677-695, 1966.
(4) Freedman, H.*: On estimating the accuracy of source "parameters." B.S.S.A. 1967.
(5) Freedman, H.*: A statistical discussion of Pn residuals from explosions Part II. B.S.S.A. 1967.
(6) Freedman, H.*: On estimating earthquake magnitude. B.S.S.A. 1967.
(7) Freedman, H.*: Seismological measurement and measurement error. B.S.S.A. 58-4, 1968.
(8) Freedman, H.*: Group analysis of variance for earthquake location and magnitude, (with Bruce Bolt). Nature 217:5223, 1968.

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(10) Grossman, E., Walchek, A. and Freedman, H.*: Tetracyclines and permanent teeth: the relation beeween dose and tooth color. Pediatrics 47(3), March 1971.
(11) Fisch, I.R., Freedman, S.H.* and Myatt, A.V.: Oral contraceptives, pregnancy, and blood pressure. J.A.M.A. 222(12): 1507-1510, December 18, 1972.
(12) Freedman, S.H.*, Ramcharan, S., Hoag, E. and Goltfien, A.: Some physiological and biochemical measurements over the menstrual cycle. In: M. Ferin, et al. New York, John Wiley & Sons, Inc., 1974. pp. 259-275.
(13) Fisch, I.R., Freedman, S.H.* and Pellegrin, F.A.: Effect of oral contraceptives on the thromboelastogram. Clin. Pharmacol. Ther. 14(2): 238-244, 1973.
(14) Fisch, I.R., Freedman, S.H.*: Oral contraceptives and the red blood cell. Clin. Pharmacol. Ther. 14(2): 245-249, March-April 1973.
(15) Freedman, S.H.* and Anderson, N.E.: Spirometry and oral contraceptives. Am. J. Obstet. Gynecol. 116(5): 682-688, July 1, 1973
(16) Fisch, I.R., Freedman, S.H.*: Oral contraceptives, ABO blood groups, and in vitro fibrin formation. Obstet. Gynecol. 46*4): 473-479, Oct. 1975.
(17) Fisch, I.R., Freedman, S.H.*: Smoking, oral contraceptives, and obesity. Effects on white blood cell count. J.A.M.A. 234(5): 500-506, Nov. 3, 1975.
(18) Freedman, S.H.* and Fisch, I.R.: Automated multitest laboratory phases and quality control procedures. In: S. Ramcharan (ed.), The Walnut Creek Contraceptive Drug Study, vol. 1. DHEW Publ. No. (NIH) 74-562.
(19) Freedman, S.H.* and Fisch, I.R.: Oral contraceptives, pregnancy and the leukocyte count. In: S. Ramcharan (ed.), The Walnut Creek Contraceptive Drug Study, vol. 2.
(20) Freedman, S.H.*, Fisch, I.R. and Pellegrin, F.A.: Application of thromboelastography to population screening programs. In: S. Ramcharan (ed.), The Walnut Creek Contraceptive Drug Study, vol. 2.

(21) Swan, S.H. and Brown, W.: Sterilization and cervical cancer. Letter to the Editor. New Engl. J. Med. 401:301, 1979.
(22) Swan, S.H. and Brown, W.: Oral contraceptive use, sexual activity and cervical carcinoma. Am. J. Gynecol., 139(1):52-57 Jan. 1981.
(23) Swan, S.H.: Risk of inflammatory disease in oral contraceptive users. Letter to the Editor. Lancet 8250:809, Oct. 10, 1981.
(24) Swan, S.H. and Petitti, D.B.: A review of bias and confounding in epidemiologic studies of cervical neoplasia and oral contraceptive use. Am. J. Epid. 115(1): 10-18, Jan. 1982.
(25) Swan, S.H.: Establishing causation: the role of epidemiologic evidence. In: A. Gelfand (ed.), Proceedings of the ASA Workshop on Law and Justice Statistics. Toronto 1983, US Govt. Printing Office.
(26) Rudolph, L. and Swan, S.H.: Reproductive hazards in the microelectronics industry. State of the Art Reviews: Occupational Medicine 1(1):135-144, Jan.- March 1986.
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(29) Swan, S.H. Diethystilbestrol and Vaginal Clear Cell Adenocarcinoma. Letter to the Editor, American Journal of Medicine 83:372-374, August, 1987.
(30) Swan S.H., Commentary on: Uses of Epidemiological Information in Pollution Episode Management by Clark Heath. In: Proceedings of the First International Conference on Environmental Epidemiology, Pittsburgh Pa. June, 1987.
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(32) Harnly ME, Swan SH, Holly EA, Kelter A, Padian N. Temporal trends in the incidence of non-Hodgkin's lymphoma and selected malignancies in a population with a high incidence of acquired immunodeficiency syndrome (AIDS). Am. J. of Epid. 128:(2) 261-266.

GOVERNMENT DOCUMENTS CO-AUTHORED

(1) State of California, Health and Welfare Agency; Department of Health Services, Guidelines for Chemical Carcinogen Risk Assessment and their Scientific Rational. November 1985.
(2) State of California, Health and Welfare Agency, Department of Health Services, Pregnancy Outcomes in Santa Clara County 1980-1982: Reports of Two Epidemiological Studies, Jan 1985.
(3) State of California, Health and Welfare Agency, Department of Health Services, Pregnancy Outcomes in Santa Clara County 1980-1985. May 1988.
(4) State of California, Health and Welfare Agency, Department of Health Services, Water Exposure and Pregnancy Outcomes. May 1988.

UNITED STATES DISTRICT COURT
For the District of Columbia

NO. 83-3504

Sekou Ealy, et al.,

Plaintiffs,

v.

Richardson-Merrell, Inc.,

Defendants.

July 8, 1987
Courtroom 7
Washington, D.C.

The above-entitled matter came on for trial before the Honorable June L. Green at 10:00 a.m.

Reported by: Bonnie L. Gahagan

Dawn Copeland
Official Reporter
Phone (202) 535-3397
Room 4806-B, U.S. Courthouse
3rd and Constitution Avenue, N.W.
Washington, D.C. 20001

[3523]
MR. NACE: Call our witness?
THE COURT: Okay.
(In open court.)
MR. NACE: Your Honor, we are going to call Dr. Shanna Swan as our witness, as soon as she comes in.

Whereupon --

SHANNA HELEN SWAN,

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. NACE:

Q. Doctor, give us your full name, please.
A. Shanna Helen Swan
Q. S W A N?
A. S W A N.
Q. I just said doctor. Are you a medical doctor?
A. I am not.
Q. You are an epidemiologist?
A. And biostatistician.
Q. Do you have a Ph.D.?
A. In statistics.
Q. Before I get to that, I just want to ask you, do you treat patients?

[3524]

A. No.
Q. Do you go to nursing homes one or two days a week to treat patients?
A. No.
Q. Do you practice in a field of reproductive epidemiology?
A. I do.
Q. Full time?
A. Yes.
Q. For whom?
A. I work for the State of California and I study -- well,

I am in charge of a large unit whose job it is to study the effects of environmental pollution on women's reproductive health; that is, their risk of spontaneous abortions, birth defects and other adverse pregnancy outcomes.

Q. Is that your full-time occupation?
A. It is.
Q. Do you consult with either drug companies or plaintiffs' attorneys two or three days a week?
A. No.
Q. Okay.
A. Although I do consult.
Q. You do consult?
A. Yes.

[3525]

Q. Let me ask you a little bit about your education. Where did you go to college?
A. I graduated from the City College of New York in mathematics.
Q. Where -- did you do additional training?
A. I did. I got a Master's in biostatistics from Columbia University.
Q. In New York?
A. In New York.
And then I got a Ph.D. in statistics at the University of California at Berkeley.
Q. Is that a Ph.D. where you worked with statistics? Is that right?
A. It was actually theoretical statistics.
Q. Is a Ph.D. given in what is called theoretical statistics.
A. Right.
Q. Do you have a Ph.D. in philosophy?
A. Doctor of Philosophy it is called.
Q. Doctor of Philosophy?
A. Yes.
Q. How does that relate to the Ph.D. that you told us about in theoretical statistics?
A. That is a the degree, Doctor of Philosophy in statistics.

[3526]

Q. I have to ask, when you got your Ph.D., did you have to do a particular thesis on a particular topic?

A. Yes.

Q. Could you tell us what your topic was?

A. Well, it was a topic in abstract probability theory and it was called the limiting distribution of random sums of independent rand variables.

Don't ask me to explain.

Q. I won't. About when did you get your Ph.D. in the statistics area?

A. In 1963.

Q. After you got your Ph.D. in statistics, did you become involved in the world of academics?

A. Yes, I did.

Q. As a professor eventually?

A. The highest academic degree I held was associate professor.

Q. Where did you teach?

A. I taught at the University of California at Berkeley, California State University, Sonoma, and also for two one-year stints, if you will, at the University of Copenhagen in Denmark and the University of Tel Aviv in Israel.

[3527]

Q. What subjects were you teaching?

A. I taught areas of statistics, biostatistics, epidemiology, mathematics.

Q. What is the relationship between biostatistics and epidemiology and mathematics?

A. Mathematics is the foundation, if you will, for all of those sciences as it is for physics or chemistry, so that is kind of the ground, and then on top of that is the theory of statistics which deals with random phenomena, things that are not certain. In particular -- that could be batting averages or cars, but it also could be health, and if you go into health and biology with statistics, that is biostatistics, and then if you want to design and carry out studies to address questions of causes of disease, that is epidemiology.

So, if you will, it is kind of a pyramid.

Q. They are all interrelated, then, in some fashion?

A. Yes, they are.

Q. So you need an understanding of statistics in order to teach epidemiology?

A. Absolutely.

Q. And to understand the meaning of epidemiology findings?

[3528]

A. Yes.

Q. Up until what year roughly were you involved in teaching?

A. I am still, although -- I am now an adjunct lecturer, unpaid lecturer, at the University of California, and that is for the technical reason that I work for the state and University of California is a state school, so I cannot be paid twice by the state, so the Department of Health gives me what is called release time, allows me to use some of my time that they pay me for to go over [to] the campus and teach.

Q. What do you teach?

A. I teach in the School of Public Health in the graduate program and I teach biostatistics and epidemiology.

I should add that I am doing that less and less as my work at the state gets more and more demanding, so probably this year I will just do, I don't know, six, eight lectures, something like that.

Q. In a school year?

A. Right.

Q. Let's --

A. Excuse me, and I also have Ph.D. students.

Q. You have Ph.D. Students?

[3529]

A. Students who are getting their Ph.D. theses under my supervision.

Q. I see. They will be getting their Ph.D.'s in statistics and biostatistics or something like that, that area?

A. Mostly epidemiology, but some biostatistics or some jointly biostatistics and epidemiology.

Q. Currently, then, what is your actual title and where do you work?

A. My title is chief of the health assessment and

surveillance unit, it is a long one, of the epidemiological studies and surveillance section of the California Department of Health Services.

Q. What do you do there?

A. What I do there is study reproductive health, particularly -- well, spontaneous abortions and birth defects in relation to exposures in the air and in the water, but also in general causes of adverse reproductive outcomes.

Q. Does this deal, then, with exogenous substances?

A. Yes.

Q. I think we have heard about exogenous substances before.

[3530]

Since about when have you been chief?

A. Around January -- well, the end of '81, I believe.

Q. Prior to that time, what did you do?

A. Well, I only joined the state in September of '81, and the first few months I wasn't unit chief, I was biostatistician, and then I was made unit chief, but before that I was the head of the graduate training program in the School of Public Health in biostatistics and epidemiology.

Q. Have you served as a senior biostatistician?

A. Yes.

Q. What is a senior biostatistician and where did you serve?

A. A senior biostatistician is simply the top, you know, a top biostatistician on a project as opposed to more junior biostatistician and I worked with a large study, a study of oral contraceptives and their noncontraceptive side effects in a large cohort of women in Kaiser, which is a prepaid health plan in California.

Q. Have you also been a consultant in that area?

A. Yes, I have.

[3531]

Q. To whom?

A. I have been a consultant to the World Health Organization, to the Food and Drug Administration, to the National Institutes of Health, and that is all.

Q. When you were with the World Health Organization

as a consultant, where were you located?

A. In Bangkok.

Q. Thailand?

A. Yes, that was just a short consultation.

Q. Doctor, do you belong to some professional societies that deal with epidemiology and biostatistics?

A. Yes.

Q. Let me just ask you about a few of them. Do you belong to the American College of Epidemiology?

A. Yes.

Q. What is that?

A. It is a professional society that you are elected to.

Q. Who belongs to that generally?

A. Epidemiologists.

Q. Do you belong to the American Statistical Association?

[3532]

A. I do.

Q. Do you belong to the Society for Epidemiological Research?

A. I do.

Q. What is that?

A. That is another professional epidemiology society.

Q. Do you belong to the American Association for the Advancement of Science?

A. Not any more.

Q. Not any more?

A. No, got too expensive.

Q. How about the Institute of Mathematics Statistics?

A. I do.

Q. How about the Biometrics Society?

A. Yes.

Q. What is a Biometric Society?

A. Well, biometrics is another name for biostatistics, is it is a biostatistical organization.

Q. Do you still belong to the American Public Health Association?

A. Oh, yes.

Q. How about the Phi Beta Kappa?

[3533]

A. Yes.

Q. What is Phi Beta Kappa?

A. It is an honor society that you are elected to if you grades are high enough.

Q. In School?

A. Yes.

Q. Have you served as a reviewer for any epidemiological publications?

A. Yes.

Q. Which ones?

A. The American Journal of Epidemiology and epidemiological reviewer for American [J]ournal of Public Health, and I am a reviewer for some medical journals as well.

Q. Have you reviewed for the American Statistical Association, their journal?

A. Yes.

Q. Are you a member of any committees that deal with statistics?

A. Yes.

Q. What would that be?

A. I am a member of the committee of the American Statistical Association called the law and justice committee, and also I serve on various study sections for the National Institute of Health.

[3534]

Q. What is a study section?

A. A study section is a group of people who are appointed to serve for three or four years to review applications for funding for research so scientists send in their grant or contract applications and this committee meets three times a year here in Bethesda actually to decide who should get money.

Q. That is for NIH?

A. Actually, my study section is with the National Center for Health Services Research, and I have also been on special study sections for the National Institutes of Health. Those are study sections around a particular problem rather than meeting over a period like three or four years.

Q. Have you published in the field of epidemiology and

biostatistics and statistics?

A. Yes, I have.

Q. Approximately how many times?

A. 20, 25. I have a couple of more recent articles.

Q. Okay. Could you just tell us some of the areas that you have published in that might be somehow involved with reproductive health or reproductive epidemiology?

[3535]

A. Actually I just gave a paper on the effects of a chemical exposure in cooking oil and did a critique of a paper in Taiwan which caused birth defects in children. I gave a paper, also, last month, invited paper on the future of environmental epidemiology, basically, future directions for environmental epidemiology.

I did a large paper report which is now coming out as a -- in a journal on spontaneous abortion and birth defects in connection with contaminated drinking water in a south base community, Silicon Valley, where they make chips.

Q. Computer chips?

A. Computer chips

I had a paper on tetracycline and children's teeth.

Q. You said you were invited to give a paper. I think that was basically your language. What does it mean when you are invited to give a paper?

A. Well, whoever is planning a session feels that you are an expert and they want you to talk about the subject.

Q. You have been asked to do that at epidemiological gatherings?

A. Yes.

[3536]

Q. Doctor, have you co-authored or authored any government documents that pertain to pregnancy and pregnancy outcomes?

A. Yes.

Q. For which government?

A. This State of California.

Q. Did you actually publish an abstract with respect to Bendectin?

A. I published an abstract and I presented two papers.

Q. Okay. Now, when you say you presented two papers, would you explain to us how that comes about, who you present them to and what it means when you present papers?

A. Well, one of these was for the Society of Epidemiological Research. That is the organization you asked me about before, and in February there is a collar for abstract, if you want to give a paper, beginning of June you send in your abstracts and your abstracts are reviewed by epidemiologists. They select, I would say, 10 to 15 percent of those submitted. I am guessing at the number, but it is getting very difficult to get an abstract accepted. And then you are asked -- you are assigned a session to present your paper at.

[3537]

That is generally the same procedure that you go through for the other organization, the American Public Health Association which presents -- has a meeting in October, so you send you abstract in and reviewed and then it gets selected and then you present your paper.

Q. Before you have an abstract published, is there "a peer-reviewing process" that it goes through?

A. Definitely.

Q. That peer-reviewing process is what?

A. The review and selection of your abstract for the meeting, and if you pass that review, then because you were given at the meeting, you will have your abstract published.

Q. Doctor, we have heard names in this courtroom. Kenneth Rothman. Do you know Dr. Rothman?

A. I do.

Q. Do you know Dr. Jose Cordero? Do you know him?

A. Yes.

Q. We have heard the name Brenda Eskanazi. Do you know Brenda Eskanazi?

A. Yes, I do.

[3538]

Q. Is that Dr. Eskanazi?

A. Yes.

Q. Allen Mitchell, Dr. Allen Mitchell. Do you know him?

A. Yes, I do.

MR. NACE: I would offer Dr. Swan as an expert in the field of epidemiology and biostatistics.

THE COURT: Questions?

EXAMINATION ON THE VOIR DIRE

BY MR. AUSTRIAN:

Q. Good afternoon, doctor.

A. Hello.

Q. As I understand it, you are not a medical doctor, is that correct?

A. That is right.

Q. You have no medical training or medical license?

A. Correct.

Q. When it comes to diagnosing or treating or caring for patients, you have no hands-on experience; is that true?

A. Right.

Q. Your degree is in mathematics and statistics, correct?

[3539]

A. Right

Q. You are not a teratologist or pharmacologist?

A. Correct.

Q. And you have no expertise in the field of toxicology?

A. Correct.

Q. Toxicology is a study of the effects of drugs on humans; is that true?

A. Yes, but I also study the effects of drugs on humans.

Q. I understand that, but you are not a toxicologist?

A. I am not a toxicologist.

Q. Now, you have never collected data, set up a protocol and carried out an epidemiological study on Bendectin, have you?

A. Not on Bendectin.

Q. You have never done a cohort study on Bendectin, have you?

A. No.

Q. You have never done a case control study on Bendectin, have you?

A. Correct.

Q. Is that true?

[3540]

A. True.

Q. What you have done is reanalyze data by a governmental data base, the Center for Disease Control; isn't that correct?

A. I have done that and I have also done an analysis of the literature on Bendectin.

Q. I understand, but in terms of the abstract that you mentioned earlier, this was a reanalysis of data done by the United States Center for Disease Control?

A. Correct.

Q. And that is the Center for Disease Control is a governmental agency, federal agency; is that correct?

A. Yes, yes.

Q. Now, when you did your reanalysis, you were not employed by the CDC, or Center for Disease Control, were you?

A. No.

Q. That reanalysis which resulted in the abstract was not in any way sponsored by the federal government, was it?

A. No.

Q. In fact, the reanalysis that you did was funded by plaintiffs' lawyers suing Merrell Dow;

[3541]

isn't that correct?

A. That is correct and I should add that I so stated both times I presented the paper.

Q. In fact, when you presented your paper, you said you have a bias because the reanalysis of data that you did was funded by a plaintiffs' lawyer; isn't that correct?

A. That is not correct. What I said, and what I believe is correct for people who are paid by interested parties to do is to make the audience aware of the funding source because of the potential for bias.

Q. The fact that you were funded by plaintiffs' law firm does not appear in the abstract that you published; isn't that correct?

A. That is correct.

Q. The funding was approximately $15,000 by the plaintiffs' law firm for your reanalysis; isn't that correct?

A. I don't recall. That sounds about right.

Q. That $15,000 does not include statements that you

have sent to plaintiffs' counsel for assisting in giving testimony, does it?

A. I don't recall.

Q. Now, in fact, for about one year prior to

[3542]

July of 1984 you were spending at least one day a week consulting with lawyers; isn't that correct?

A. I don't recall.

Q. Would it be fair to say that in terms of the reanalysis that you did, it was only because of the litigation that made that possible?

A. It would have been possible for me to get the data base had I had a lot of money, but it is expensive.

Q. I understand.

Now, can you tell me whether after you received or did your reanalysis you wrote up a report of your study?

MR. NACE: I don't mind him asking these questions, but I don't believe on voir dire it is proper.

MR. AUSTRIAN: He asked questions in terms of the abstract and I am entitled, I think, to ask whether she ever wrote up the results of her study?

MR. NACE: I just don't believe it is proper voir dire.

THE COURT: Overruled. Go ahead.

BY MR. AUSTRIAN:

Q. Did you ever write up your results of your study?

[3543]

A. No, I have not yet.

Q. Did you ever submit your study to a peer-review journal to be published?

A. I have not yet, but I would like to also add that I also have not yet submitted the results of the study I did for the state, two studies I did for the state. It is just -- I don't have time.

Q. You started your analysis, did you not, in 1982?

A. That is correct, and I started the Fairchild study in 1982, also, and that is not published and that was certainly something I was paid for by the state.

Q. In terms of the people who assisted you with the reanalysis, is it also true that some of them were employees of

the plaintiffs' law firm?

A. I would say probably 2 or 3 percent of the work was done by employees by the plaintiffs' law firm at the beginning and then I took that data myself away from that law firm.

Q. Now, the data that you did the reanalysis had nothing to do with your employment at the State of California, did it?

A. No.

Q. You have been involved in at least 23

[3544]

cases involving actions against pharmaceutical companies, have you not?

A. I don't know.

Q. Would that be a fair statement?

A. I don't recall.

Q. When you first began your reanalysis, you had no written protocol for that study, did you?

A. CDC had a written protocol.

Q. You did not have a written protocol for that study, did you, doctor?

A. The answer is no, but I would like to explain. There are -- it is not appropriate to have a protocol for a reanalysis of an existing data base. This is done all the time.

For example, Dr. Mitchell continually goes back and reanalyzes his data, Dr. Cordero does that and we do that in the state, and every time you do a reanalysis, you don't write another protocol. It is not done.

Q. When you reanalyzed the data for the CDC, you used a different definition for the first trimester, different definition of the items to be used in the study and different definition for controls?

A. Those were written down specifically.

Q. Those were not written down before the

[3545]

study was --

A. Yes, they were.

Q. You started you reanalysis before the CDC was published in the Journal of the American Medical Association in 1980?

A. No, before my reanalysis was published.

Q. Your reanalysis has never been published in a peer-review journal, is that correct?

A. The abstract was.

Q. No, your reanalysis and the discussion of the data has never been --

A. I said that, but you asked me whether the definitions were written down before my results were published and I said yes.

Q. Your results have never been published in a peer-review journal?

A. An abstract of them have been published, a paper on it has not been published. We can talk about abstract and paper.

Q. Just so we are clear, I am talking about paper, a paper.

A. No, a paper has not been published.

Q. You have never written up the study or paper so that someone can actually look at and consider how you actually arrived at your data,

[3546]

isn't that also true?

A. That is true, although I did discuss it on many occasions with Dr. Cordero and with a number of my colleagues both privately and at those two meetings, so certainly in the epidemiological view.

Q. There is no place in medical literature where you have put together a report describing your reanalysis and how you got the figures and the definitions that you used; isn't that correct?

A. That is correct.

MR. AUSTRIAN: Nothing further.

May we approach, your Honor?

THE COURT: Yes.

(At the bench.)

MR. AUSTRIAN: I object to any testimony concerning the reanalysis of data, the Center of Disease Control data.

First, it is certainly not appropriate rebuttal to have a contention made that a study for reanalysis supports plaintiffs' case and should be done in the case in chief so that the defendant can in fact respond to it and not present it for the first time in the

rebuttal part of the case.

This witness could have been brought here

[3547]

in the case in chief and presented any data she had to suggest that Bendectin was associated with birth defects.

Secondly, in this testimony was not done independently, it was paid for by the plaintiffs' law firm, not Mr. Nace's law firm --

THE COURT: You said you would make that clear, but you haven't.

MR. AUSTRIAN: I will make that clear.

MR. NACE: I will.

MR. AUSTRIAN: I will make that clear.

THE COURT: I was disappointed.

MR. AUSTRIAN: I apologize, your Honor.

Furthermore, in terms of qualifications, she does not see children, deal with children. She is a statistician and certainly cannot give views on Bendectin's safety or lack of safety based on her background and training.

THE COURT: We have heard from so many people who haven't seen children and I don't think that would be a basis, would it?

MR. AUSTRIAN: Pardon?

THE COURT: I say we have heard from so many people who don't see children that I don't think that would be a basis, would it? Your

[3548]

objection is overruled.

(In open court.)

DIRECT EXAMINATION continued

BY MR. NACE:

Q. Doctor, I want to show you what has been marked a 438, a copy dated May 9, 1986 and I have crossed out that one section of American Association for whatever, and other than that, is that basically correct, up-to-date, except for a couple of more publications perhaps?

A. Yes.

Q. I want to ask you about the reanalysis that you were asked about. First of all, you indicated that you were funded or

it was paid for by some attorneys?

A. Yes.

Q. Was I or any member of my law firm one of those attorneys that paid for this?

A. No.

Q. I want to show you marked as Exhibit 504, and I think it is in the stack over here, I am showing you 504. Is that a copy of the reanalysis that you did as far as the abstract?

A. On page 486, the bottom right there is a copy of the abstract.

* * *

[3553]

Q. Doctor, in your field, in your position with the State of California, are you called upon to help determine the causes of birth defects?

A. Yes.

Q. What kind of data does an epidemiologist and a biostatistician use? And I don't want a 10-minute answer, just a short answer as to what kind of data do you utilize.

A. Two kinds. We utilize published data, where we pull together all the available information published. That is called secondary data collection or we do primary data collection where we go out an get new data through interviewing women, through medical records, birth certificates and so on.

Q. Now, do you yourself do in vitro studies or animal studies or work with pharmacology of drugs?

A. No.

Q. Are you aware of their relationships to determining whether or not a drug is a teratogen?

A. Yes.

Q. What is the relationship from the epidemiological standpoint?

A. We work with people in those fields in making the analysis of whether an observed

[3554]

statistical association is causal, and to do that we have employed, for example, in the state toxicologists, biochemists, animal

researchers and when we have a problem, we meet and talk about that and get everybody's input.

Q. Are decisions generally and usually made based solely on epidemiological data as to teratogenicity issues?

A. I am inclined to say never.

Q. Never?

A. Yes. I can't think of any situation where you would only rely on epidemiology. Maybe in an extreme example, but not in the course of my work.

Q. What do you mean by an extreme example? What are you talking about. I don't want a name of anything, but what do you mean by an extreme example?

A. Where the epidemiology was so impelling in and of itself that we would feel without taking the time to collect additional data, it was necessary to take an action in the interest of public health.

Q. Are decisions made that there is not an association between an exogenous substance such as a drug and a defect, are such decisions made solely on epidemiological data.

A. Again, I would have to say almost never,

* * *

[3575]

therapeutic principles and an article by Allen Mitchell. We have talked somewhat about the examples that he gives back on pages 68 and 69 regarding inconclusive positive and negative studies. To you as an epidemiologist, what is an inconclusive study?

A. An inconclusive study is one that doesn't reach traditional levels of statistical significance, but does not have the statistical power to rule out appreciable relative risks. In other words, the data could be consistent with either no effect or an effect that you were worried about.

Q. I believe Dr. Mitchell in the Yaffe book talks about on page 69 about two types of statistical analysis, a type 1 and a type 2 analysis and often a beta as he calls it.

A. Right.

Q. Are both of those analyses generally done when one is trying to determine the validity or to interpret an epidemiological study?

A. They should both be done.

Q. Why is that?

A. Because in any situation where you are doing research, you are using a sample, so you will run the risk of making a mistake. There are two

[3576]

kind of mistakes you can make. You can say that the drug is safe when it is not --

Q. Let me write something down here. Are we talking about type 1 and type 2?

A. Right.

Q. Let me do a type 1. Now, what is a type 1?

A. A type 1 is when you say that the drug is harmful when it is really safe.

Q. When you say harmful, and I will put that in quotes, when it is really safe?

A. Right, you do a study and you get a two, statistically significant, but just by the luck of the draw, it is really not an association and it is just bad luck.

Q. What is type 2?

A. The type 2 is to say that the drug is safe when it is really harmful.

Q. Safe when harmful?

A. So that would be when your study might have a relative risk which is smaller, 1.5 maybe, not statistically significant, you say the drug is safe, but in reality you miss something important.

Q. Are these types of errors?

A. These are errors, the two errors that you can make.

[3577]

Q. One is alpha and one is beta?

A. Alpha is type 1 and beta is type 2.

Q. This is an alpha sign?

A. Yes.

Q. This is a beta sign?

A. Yes.

Q. Now, when we talk about power, what does that apply to?

A. Power is just simply one minus beta.

Q. Is that a type 2 error?

A. Yes. The smaller the beta, the larger the power.

Q. Put power down here in the type 2?

A. However you want to write it, that is the fact. Power is one minus beta.

Q. One minus beta?

A. Right.

Q. What is the phrase that corresponds with the type 1 error, alpha error?

A. That corresponds to the confidence interval.

Q. Confidence interval. Okay. Now, the various studies that have been talked about, I believe, about the cohort, Jick, Aselton, Heinonen, Morelock --

[3578]

A. Yes.

Q. -- Jick, Aselton, Heinonen and Morelock, those studies, the way they are designed, are they more likely to show type 1 or type 2 errors?

A. None of them controls the type 2 error.

Q. What do you mean they don't control the type 2 error?

A. In all of those the type 2 error is very large. It is at least 80 percent.

Q. At least what?

A. 80 percent.

Q. Now, what does that mean?

A. That means that there is an 80 percent chance or greater that the drug could be harmful and these studies would conclude that it was safe.

Q. All right.

A. Where harmful means in this calculation a doubled risk of limb reduction defects.

Q. When we talked about a doubled risk of limb reduction defect --

A. 100 percent more of limb reduction defects of women who took Bendectin in the first trimester. That could be happening, in these studies probably 80 percent or greater would say the drug is safe.

Q. Now, with respect to the power to detect a

* * *

[3598]

A. Well, Jick has the most power.

Q. What are the chanees of the best one then, the Jick study, finding 100 percent increase?

A. 17 -- about 17 percent, 17.6.

Q. Would it be and accepted practice by epidemiologists to rely upon a study or even four studies, none of which had a power greater than 17 percent to detect 100 percent increase to decide that a drug is safe and could not cause birth defects?

A. No.

Q. Now, doctor --

A. Let me just say that these studies altogether if you had the power of all of these studies together --

Q. You mean by the numbers?

A. Yes, if somebody instead of doing four studies had done one study with all of these numbers, you would still have a power of less than 50 percent.

Q. Meaning less than 50 percent meaning there would be less than a 50 percent chance of finding 100 percent increase?

A. Yes.

Q. Putting them all together, if you have less than a 50 percent chance of finding 100 percent

* * *

10. Affidavit of Jay H. Glasser, Ph.D and curriculum vitae (Dock. No. 188), filed Sept. 28, 1989, excerpts of testimony in *Hill v. Merrell Dow Pharmaceuticals, Inc.* (Ex. 32 to Pltfs.' Opp. to Summ. Judg.), filed Aug. 22, 1989, and excerpts of deposition (Ex. J to Merrell Dow's Reply to Pltfs.' Opp. to Deft.'s Mot. for Summ. Judg.), filed Aug. 28, 1989

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UNITED STATES DISTRICT COURT
For the Southern District of California

NO. 84-2013-G(I)

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardian Ad Litem for JASON DAUBERT, a Minor,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50 Inclusive,
Defendants.

NO. 84-2929-G(I)

MICHAEL SCHULLER, ANITA DE YOUNG, and ANITA DE YOUNG as Guardian ad Litem for ERIC SCHULLER,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50, Inclusive
Defendants.

[2] **AFFIDAVIT OF JAY H. GLASSER**

My name is Jay H. Glasser and I state as follows:

1. I have a Ph.D. in experimental statistics which I obtained after receiving my Bachelor's Degree from the University of Connecticut with a major in zoology and a minor in mathematics. Thereafter, I received a Master of Science in biostatistics from the School of Public Health at Columbia University, and then completed my formal education by receiving my Ph.D. and doing the necessary studies at the University of North Carolina and at North Carolina State University.

I am currently a professor of biometry and computer sciences and was the convener of the biometry module at the University of Texas, School of Public Health and am currently Co-Director of the Graduate Program for Health Technology Assessment.

Biometry is a study of and the design of studies dealing with the life sciences to evaluate medical experiments, population studies, to provide the machinery and methodology of such studies, primarily with application in the health fields, community health and public health. Biostatistics is the related aspect of biometry. Epidemiology is the study of the distribution of diseases in a population, both in time and space, with other modifiers, such as social conditions. Biometry and biostatistics are the fundamental contributors providing much of the mathematical background and the

[3]

theoretical background in the techniques that are used in epidemiology. Mathematics is the fundamental science; biostatistics

and biometry arise out of trying to apply analytic principles to study the life processes; and epidemiology involves looking at disease distributions.

My teaching experience has included teaching epidemiology, statistics, biometry, and biostatistics.

I have been a member of the Population Association of the Society for Epidemiological Research, of the American Statistical Association, The Royal Statistical Society, the American Public Health Association, various inter-American statistical associations, and I have been elected to be head of the Social Statistics Section of the American Statistical Association. I have held several positions concerning grant review committees for national government, and I have worked with the United Nations on numerous assignments abroad. I have also served as a peer reviewer for such journals as the New York State Journal of Medicine, Medical Care, and The American Journal of Public Health, etc. I have served on committees with respect to areas that involve epidemiology, including committees for the National Center for Health and Services Research and Health Care Technology; for the Department of Health and Human Services; and I served as a consultant to the National Center for Health Statistics, the National Institute on Aging, and others. One of the recent courses that I taught was titled "Epidemiology, Biostatistics,

[4]

and Public Health."

I have more than 30 articles in refereed journals in the fields of biostatistics, epidemiology, and biometry.

2. I have reviewed the epidemiology studies that pertain to Bendectin.

3. I have been appointed by the Federal Bankruptcy Court in the Dalkon Shield cases to do epidemiological analysis.

4. In examining epidemiology studies, one must keep in mind that there are numerous difficulties associated with trying to do such studies with expected birth defects. These difficulties include precisely what drugs were given in [addition] to the drug being tested and when were they given; what are the characteristics of the persons involved; what is the reproductive history of the individuals in the study; what is the reliability of the study, etc. When one is looking at a defect that is rare, these difficulties increase in magnitude with respect to the drug being examined.

5. In reviewing the various epidemiological studies, one must utilize one's training, education and experience as an epidemiologist, and analyze the data in order to be able to render an intelligent opinion. One must look at this study closely, analyze it,

and determine the quality of its methodology.

When one looks at the epidemiology studies pertaining to Bendectin, one finds that there are in fact studies that do

[5]

show a statistically significant association between Bendectin and birth defects, even at the 95% confidence level. Moreover, because of the weakness of the epidemiological information one needs to look at all of the available epidemiological data in order to determine whether or not a drug is generally a teratogen. In that regards, all the studies are helpful and informative in some regard.

I have reviewed numerous epidemiological articles including those by Aselton, Eskenazi, Cordero, Jick, etc.

6. In my opinion, it would not be good, and generally accepted, and reasonably accepted, epidemiological practice to ignore data that might be in an article dealing with one injury such a pyloric stenosis in maternal Bendectin exposure or an article that dealt with heart defects or cleft palate if one was attempting to determine whether o[r] not a drug was capable of causing a defect in the limbs. It would be wrong to ignore those studies. Standard practice would be to examine such studies.

One must always keep in mind that when one looks at the epidemiology studies one primarily deals with statistical data of the population and not for individuals. A statistical association that may be made at the 95% confidence level does not by itself mean that a member of that group developed a defect merely because he was in the positive group. Likewise, the statistical data therefore can only give a guideline with respect to an analysis on whether or not a drug is a

[6]

teratogen. In other words, association means that one thing is related to the other, but it does not mean that the one thing causes the other. Likewise, a failure to show a statistical association does not mean that there is not a causal connection.

When one looks at the epidemiological dat[a] on Bendectin and using my education, training and experience, it is my opinion that within a reasonable degree of epidemiological certainty that there is evidence that shows that there is a statistical association between Bendectin and various birth defects. In making this analysis, I used the methodology and techniques that are generally and reasonably relied upon by persons who are trained with respect to biostatistics, biometry, and epidemiology.

7. When one looks at the studies known as Cordero, Eskenazi, and McCredie, one finds that in each case the data in that study showed a point estimate of the relative-risk that was greater than

one which indicates that the risk of developing a child with a limb defect was greater when Bendectin was taken than when it was not taken. None of the studies could be interpreted as being negative studies. Further, when one looks at each of these three limb reduction studies, considering the relative risks that are developed, considering that various problems and limitations with the studies exist, using my education, experience and training with respect to public health, epidemiology, biostatistics,

[7]

biometry, and utilizing the methodology that is generally and reasonably relied upon, within a reasonabl[e] degree of epidemiological certainty, there is a statistical association between Bendectin and limb defects. Moreover, when one looks at the limb studies just referred to along with the other studies on cleft palate, pyloric stenosis, and heart malformations, once again using my education, experience, and training, and the methodology that is generally and reasonably relied upon in the field, it is my opinion within a reasonable degree of epidemiological certainty that Bendectin is associated with limb defects and other birth defects, as well.

8. A review of the Jick data that was collected and supplied to me shows that such is in fact another collection of a body of data that statistically significantly associates Bendectin and limb defects.

9. Further, based on my education, training and experience and reviewing the epidemiological articles that pertain to Bendectin, it is my opinion that within a reasonable degree of epidemiological certainly utilizing the techniques that are generally and reasonably relied upon by biometrists, and biostatisticians that Bendectin is within a reasonable degree of epidemiological certainty associated with congenital disorders, including limb defects.

10. To the best of my knowledge, I have reviewed all of the published epidemiological data on Bendectin.

[8]

11. In sum, when one uses one's education, training and experience and generally and reasonably relied upon methodologies for review, I am of the opinion that within a reasonable degree of epidemiological certainty that there is in fact a statistical association between Bendectin and birth defects including limb defects.

/s/
Jay H. Glasser

STATE OF

COUNTY OF

Subscribed and sworn to before me this 27th day of September, 1989.

/s/
Notary Public

CURRICULUM VITAE

Jay Howard Glasser, Ph.D., Associate Professor
Biometry and Computer Services
School of Public Health
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Educational Qualifications:

1957 B.S.
University of Connecticut
Zoology - Mathematics
1960 M.Sci.
Columbia University
Biostatistics
1967 Ph.D.
North Carolina State University
Experimental Statistics

Professional Experience:

Convener - Biometry Discipline, School of Public Health, The University of Texas, Houston, Texas, September 1984 - Present.
Associate Professor of Biometry and Computer Sciences, School of Public Health, The University of Texas, Houston, Texas, September 1969 - Present.
Visiting Senior Lecturer, Department of Community Medicine, St. Thomas' Hospital Medical School, London, England, 1974-1975.
Senior Investigator, Kaiser (Portland) Health Service Research Center, Kaiser Foundation Hospitals, 1970 - 1982.
Visiting Faculty in Graduate Summer Session of Statistics in the Health Science, School of Public Health, University of California at Berkeley, 1971 - 1972.
Consultant in Residence (Washington, D.C.), National Center for Health Services Research and Development, Summer 1970; National Center for Health Statistics, Summer 1967, 1968 and 1976.

Assistant Professor, Department of Biostatistics and Carolina Population Center, University of North Carolina, Chapel Hill, North Carolina, 1967-1969.
Instructor, Department of Biostatistics, University of North Carolina, Chapel Hill, North Carolina, 1964-196[ ].
Visiting Lecturer, Duke University, School of Nursing, 1963-1969.
Assistant Statistician, New York City Health Department, 1957-1958.

Recent Consultant Positions:

American Association for the Advancement of Science
American Association for Vital and Health Statistics
Baylor College of Medicine (Department of Pediatrics) and Texas Childrens Hospital
McDonnell Douglas Corporation
National Academy of Science (Institute of Medicine)
National Center for Health Service Research and Health Care Technology Assessment (DHHS)
National Center for Health Statistics (DHHS)
National Institute on Aging
National Institute of Heart, Lung, and Blood Institute
National Institute for Occupational Safety and Health
United Nations
United States Courts Eastern District of Virginia, (Robins-Dalkon Shield Litigation)
Veterans Administration
World Health Organization (Geneva, Switzerland)

Honors and/or Special Awards:

Research Scientist - Career Development Award (Health Services Research) U.S. Department of Health, Education and Welfare, 1971-1976.
Fellow, Royal Statistical Society, United Kingdom, 1974.
Fellow, American Public Health Association, 1969.
Sigma Xi, 1968.
National Institute of Health Fellowship, 1958-1964.
Public Health Traineeship, 1959-1960.
Research Fellowship, Marine Biological Laboratory, 1956.

Professional Societies:

American Public Health Association
Committee on American Statistical Association (1987-89)
Biometrics Society
Inter-American Statistical Institute

Professional Society and Academic Offices:

Chair, Statistics Section, American Public Health Association, 1986-87.
Member: Committee on International Relations in Statistics, American Statistical Association, 1987- 1989
Member: Committee on Quality Assurance in Patient Care, The Medical School, The University of Texas Health Science Center, 1987-Present
Chair-Elect and Program (Chair, Statistics Section, American Public Health Association, 1985-1986
Convener, Biometry Faculty, School of Public Health, The University of Texas, 1984-Present
Associate, Program in Health Care Technology and Ethics, University of Texas Health Science Center, 1984-Present
Executive Board, American Statistical Association, Social Statistics Section, 1981-1982 (ex-officio).
Chair, Membership Committee, American Public Health Association, Statistics Section, 1981-1982.
Chairman, American Statistics Association Social Statistics Section, 1980-1981.
Action Board, American Public Health Association, 1975-1977 term.
Convenor, Health Services Organization Faculty, School of Public Health, the University of Texas, 1973-1974, 1975-1977.
Statistics Section Council, American Public Health Association, 1970-1973.
Chairman, Academic Affairs Committee, School of Public Health, The University of Texas, 1969-1970.
Faculty Council, The University of North Carolina 1968-1971 term (an elective office).
Program Committee and Chairman, Statistics Section, American Public Health Association, 1968-1969.

National and State Advisory and Review Committees:

Expert: United States Court, Eastern Division of Virginia (Epidemiological and Statistical evidence for litigation of the Robins-Dalkon Shield IUD claims before the Court), 1986-present.
Chairman, Family Planning, adhoc Special Review Committee, Office of Population, Department of Health and Human Services (DHHS), 1983-1987.
Member, adhoc Nursing Research Review Group, National Institutes of Health, 1985 and 1986.
Member, Health Services Developmental Grant Review Subcommittee, National Center for Health Services Research (DHHS), October 1982 - July 1986 term.
Member, ad hoc Program Grant Review Committees, National Institute on Aging (DHHS), 1982, 1984, 1985.
Chairman, Special Review Group Health Hazard Evaluation and Occupational Health Surveillance, National Center for Occupational Health and Safety (DHHS), 1980-1981 and 1982.
Member: Nursing Study, Trends and Forecasting Panel, Institute of Medicine, National Academy of Sciences, 1981.
Member: Health Planning Center Council, Region VI Center for Health Planning, 1976-1979.
Member: The University of Texas System Group on Health Policy Development, 1978-present.
Health Services Research Review Committee, National Center for Health Services Research (DHHS), July 1977 - June 1981 term.
Task Force on Training, National Center for Health Statistics, 1976-1978.
HMO Advisory Committee, Health Resource Department, State of Texas, 1975-1976.
Research in Nursing and Patient Care Review Committee, Division of Nursing (DHEW), July 1970 - June, 1974 term.
Member of Federal-State-Local Data Systems Review Committee, National Center for Health Services Research and Development, 1972-1973.

Miscellaneous:

Committee on Federal Statistics for Public Health, American Public Health Association, 1981 - present.
Health Profiles for Hazardous Waste Disposal Sites and Incineration Operations. State of Missouri, 1981 - present.

Joint Ad Hoc Committee on the Assessment of National Data Resources for Biomedical Research, American Public Health Association, 1970 - 1979.
Epidemiologic Analysis Committee, National Center for Health Services Research (DHEW), 1969 - 1974.

Training, Workshop and Materials Development:

Local Coordinator and Organizer: Workshop on the National Health Centers Health Interview Survey (1987), Sponsored by the National Center for Health Statistics, DHHS.
Presenter and Resource Person: Uses of Statistical and Epidemiological Data in Legal Testimony Association of Consulting Toxicologists, 1987.
Local Coordinator and Organizer: Hispanic Health and Nutrition Examination Survey Data Tape Workshop (HHANES), 1986. Sponsored by the National Center for Health Statistics, DHHS.
Seminar Director and presenter "Microcomputers for Managers" developed and presented for The Social Security Administration (U.S.) 1984. A seminar series for managers on the use, and implementation of microcomputers in local offices. The course included hands-on instruction including modules on data processing, workflow, scheduling and word processing. No prior experience in computers was assumed.
Course Director: "Reimbursement and Rate Setting Concepts," Applied Statistics Training Institute, National Center for Health Statistics (DHHS). July 1981 and June 1982. A course on cost containment, rate setting and financial management for health care institutions and delivery agencies.
Seminar and workshop on Human Resource Development Applied to Nurse Recruitment and Retention Studies (1982).
Seminar on Cost Benefit-Cost Effective Methodology Applied to Occupational Health (1982).
A series of modular courses on Program Evaluation, Cost Benefit-Cost Effectiveness Analysis, selected topics in Demographic Analysis and Indices of Health. Development jointly with colleagues and pretested for the Applied Statistics Training Institute (National Center for Health Statistics, DHHS) (1978-1980).
Course Director: "Statistical Methods in Health Service Delivery and Administration," Applied Statistics Training Institute, National Center for Health Statistics (DHHS). Annual Presentations, 1971-1981. A course on quantitative techniques and [information] systems use and development directed to

administrators, planners and evaluators.
Developed and presented a series of education television tapes on Biostatistics (part of a course, "Foundations in Public Health"), November 1968 - January 1969.
Source Book in Health Policy Analysis and Quantitive Techniques. The use and role of epidemiological, statistical and demographic techniques in the development and evaluation of health policy (in process).

International:

Organizer and Presider, Seminar on Methods of Medical Technology Assessment, Tekmed Congress 1987, Lyon, France.
Course Director and faculty member: Epidemiology, Statistics, and Experimental Design in Public Health. Presented at the University of Panama, Republic of Panama, 1987. Sponsored by the American Association for the Advancement of Science and Consortium for Universities in Central America.
Consultant in further development and implementation of a complete registration training program and subsequent adaptation for Jamaica. This on-going project is jointly sponsored by the Registrar General's Office of Jamaica, the National Center for Health Statistics and AID-Jamaica (1980-1986).
National Conference on Vital Statistics and Registration Improvement and Training in Program Evaluation Research in Family Planning (National Family Planning Board of Jamaica and AID-Jamaica) (project pending).
Consultant: American Public Health Association. Evaluation of the Contraceptive Prevalence Study Program. Agency for International Development (1983).

Other International Consulting and Experience:

Consultant and participant: African Regional Conference on Contraceptive Prevalence Studies (Westinghouse Systems), Harare, Zimbabwe (March-April 1983).
Member and Secretary: United Nations - Expert Panel on Revision of the The Handbook on Registration and Vital Statistics, 1983-1985.
Consultant to the Ministry of Health, the United Arab Republic of Egypt for the Health Profile of Egypt. Analysis of the Health Interview and Health Examination Survey results (sponsored

jointly by the Ministry of Health and the National Center for Health Statistics (March-April 1982 and March-April 1983).

Developed a Modular Course in Vital Statistics Improvement and Civil Registration Training (with E.S. Lee). A 20-module training course in Vital Statistics and Management Techniques for Vital Statistics Improvement in Developing Nations. Developed for the VISTIM Program, National Center for Health Statistics (DHHS) (1977-1979).

Visits to Denmark, England, Israel, Norway, Sweden and U.S.S.R. to observe and meet colleagues in health services delivery, planning, administration research, and training (1974, 1975, 1977, and 1980).

Visits and consultation with WHO European Regional Office and WHO Geneva (1974-1975, 1982-1986).

Visits to Pakistan and India to study the feasibility of establishing population measurement laboratories (sponsored by the Population Center, the University of North Carolina and US-AID) (1968).

Current Duties:

Teaching: Various courses in basic and advanced topics in biostatistics, epidemiology and population research techniques and applied research in community health; planning, monitoring and evaluation. Developing modular courses and source book material in health services delivery, policy analysis, trend and forecasting analysis and technology assessment.

Consulting: General consulting in health sciences clinical trials and health services research with particular emphasis on program and study designs, survey research and information systems, analysis of data and quantitative evaluation of delivery systems. Consulting includes the use of microcomputers, workshops and seminar development to upgrade practicing health professionals' skills, epidemiological and statistical analysis of health hazards with emphasis on monitoring and legal applications.

Research: Measurement in health service research, policy analysis, technology assessment, delivery systems and community health programs stochastic models in the biological sciences and demography. Recent areas of research include utilization analysis, trend and impact analysis, epidemiological basis for population health hazards monitoring, mental health, and eldercare.

Publications:

J.H. Glasser, "Strategy for Improving Coverage, and Quality of Registration and Statistics". A chapter in Handbook on Methods for Vital Statistics and Registration. The United Nations. In press.

J.H. Glasser, "Health Statistics Surveillance Systems for Hazardous Substance Disposal" in Proceedings of the 1985 Public Health Conference on Records and Statistics, The National Center for Health Statistics, DHHS Publication No. (PHS) 86-1214 (1986)

J.H. Glasser, "Implications of the Declining Mortality for The Organization of Health Care: The Case of Jamaica" in New Developments in the Analysis of Mortality and Causes of Death, edited by H. Hansluwka, et.al. World Health Organization, Geneva, Switzerland 1986.

J. Mangaroo, J.H. Glasser, L. Roht and A. Kapadia, "Prevalence of Bone Dimineralization in The United States." Bone (Formerly Metabolic Bone
Disease and Related Research). Vol 6, March 1985, p. 135-139.

B.L. Levin, J.H. Glasser, "A National Survey of Prepaid Mental Health Services."
Journal of Hospital and Community Psychiatry. Vol. 35 No. 4, April 1984

B.L. Levin, J.H. Glasser and R.E. Roberts, "Changing Patterns in Mental Health Services Coverage Within Health Maintenance Organizations." American Journal of Public Health. Vol. 74, No. 5, May 1984.

J.H. Glasser and J. Wolfson, "Rocky Road, the Flavor of Health Services Research." Medical Care. Vol. 21, No. 9, September 1983, pp. 393-942.

J.H. Glasser, "Teaching of Statistics in Health Administration." Proceedings of the Social Statistics Section, American Statistical Association. August 1982.

J. Mangaroo, J.H. Glasser and A. Littel et al., "Networking Micro-Processors for Effective Computer Utilization in Nursing." Proceedings of the Sixth Annual Symposium on Computer Application in Medical Care IEEE Computer Society. Library of Congress No. 79-641114, p. 575, November 1982.

D. Lairson, R. Forthofer, and J.H. Glasser, "Medical Care Utilization in a Regional Prepaid Medical System. " The Annals of Regional Science. Vol . 16, No. 2, July 1982, pp. 62-72.

J . H . Glasser, "Quality and Utility of Death Certificate Data. " American Journal of Public Health. Vol. 71, No. 3, March 1981.

M. Rush and J.H. Glasser, "Lightning Risk." Reviews on Environmental Health, Vol. III, No. 3, 1981, pp. 301-313.

R. Forthofer, D. Lairson and J.H. Glasser, "Catastrophic Insurances and HMOs." Social Science and Medicine. Vol 16, No. 3, pp. 1775-1779, March 1981.

B.L. Levin and J.H. Glasser, "Mental Health Coverage Within Prepaid Health Plans." Administration in Mental Health, Vol . 7, No. 4, Summer 1980, pp. 271 -281.

D. Lairson, R. Forthofer and J.H. Glasser, "Catastrophic Illness in an HMO." Inquiry, Vol. XVI, No. 2, Summer 1979, pp. 119-130.

R. Forthofer and J. H. Glasser, "Utilization of Services of an HMO by New Enrollees." American Journal of Public Health, Vol. 69, No. 11, November 1979, pp. 1127-1131.

B.L. Levin and J H. Glasser "A Survey of Mental Health Service Coverage Within Health Maintenance Organizations." American Journal of Public Health, Vol. 69, No. 11, November 1979, pp. 1120-1125.

R. Forthofer, J.H. Glasser and N. Light, "Life Table Analysis of Membership - Retention in an HMO." Journal of Community Health, Vol 5, No. 1, Fall 1979, pp. 46-53.

J.H. Glasser, R. Roberts, O. McCrory and C. Askew, "Dental Care for Handicapped Children Re-examined: I. Dental Training and Treatment of the Handicapped." Journal of Public Health Dentistry, Vol. 38, No. 1, Winter 1978, pp. 22-34.

D. Lairson, R. Forthofer and J. H. Glasser, "Catastrophic Expenditures: Family Experience in an HMO. " Third Data Use Conference, Part [I]. Health Planning Information Series, DHEW, Publication HRP-C201-1401 (1978).

J.H. Glasser, R. Roberts, O. McCrory and C. Askew, "Dental Care for Handicapped Children Re-Examined: II. Dimensions of Dental [Practice]." Journal of Public Health Dentistry, Vol. 38, No. 2, Spring 1978, pp. 136-147.

J.H. Glasser, R. Roberts, and O. McCrory, "Specialized Training for Dentists Treating Children with Handicaps." Department of Health, Education and Welfare, Bureau of Community Health Services, Publication No. (HSA) 78-5218, 1978, pp. 119-130.

J.H. Glasser, "Research Needs for Data Applications in Health Planning." Proceedings of the Public Health Conference on Records and Statistics, 16th National Meeting, DHEW National Center for Health Statistics, DHEW Publication No. (HRA) 77-1214 (1977).

Florence Lee and J.H. Glasser, "Role of Lay Midwifery in Maternity Care in a Large Metropolitan Area." Public Health Reports, Vol. 89, No. 6, November-December 1974, pp. 537-544.

D. Basco, S. Eyres, D. Roberts and J.H. Glasser, "Epidemiologic Analysis of School Populations as a Basis for Chance in School Nursing Practice: Report of the Second Phase of a Longitudinal Study." American Journal of Public Health, Vol. 62, No. 4, April 1972, pp. 491-497.

J.H. Glasser, "Health-Information Systems: A Crisis or Just More of the Usual?" American Journal of Public Health, Vol. 61, No. 8, August 1971, pp. 1524-1530.

J.H. Glasser, "A Stochastic Model for Industrial Illness Absenteeism." American Journal of Public Health, Vol. 60, No. 10, October 1970, pp. 1936-1944.

A. Kaluzny, J. Gentry, and J.H. Glasser, "Diffusion of Innovative Health Care Services in the United States." Medical Care, November-December 1970, Vol. 8, No. 6, pp. 474-487.

J. Gentry, A. Kaluzny and J. Sprague and J.H. Glasser, "Perceptual Difference of Administrators Regarding the Importance of Health Service Programs: Implications for Education for Health Service Administration." American Journal of Public Health, Vol. 60, No. 6, 1970, pp. 1006-1017.

J.H. Glasser, "Conceptual Issues in the Selection of Statistical Techniques for the Analysis of Medical Care Utilization Behavior." HEW (National Center for Health Services Research), October 1969.

D. Basco, S. Eyeres, D. Roberts and J.H. Glasser, "Epidemiologic Analysis in School Populations as a Basis for Change in School Nursing Practice." American Journal of Public Health Vol. 59, No. 12, December 1969, pp. 2157-2167.

J.H. Glasser and P.A. Lachenbruch, "Observation on the Relationship Between Frequency and Timing of Intercourse and the Probability of Conception." Population Studies, Vol 22, No. 3, 1968.

A. Kluzny, J. Gentry and J.H. Glasser, "Innovation in Health Care Research and Plan of Project Studies. " Health

A. Kluzny, J. Gentry Organizations: Review of Services Research, Vol 3, No. 4, Winter 1968, pp. 316-326.

"A Stochastic Model for Industrial Absenteeism." Unpublished doctoral dissertation, North Carolina State University, April 1967.

Miscellaneous Publications:

B.L. Levin and J.H. Glasser, "Preliminary Results from the 1982 National Survey of Psychiatric Services and Coverage Benefits With Health Maintenance Organizations." In D.Y. Patterson (ed): Report of the Task Force on Health Maintenance Organizations . American Psychiatric Association . In press.

J.H. Glasser, E.S. Lee and R. Forthofer, "Discussion of Methodologic Papers of the National Center of Health Statistics." Proceedings of the Social Statistics Section. American Statistical Association, August 1978.

Recent Commissioned or Invited Papers and Seminars

J.H. Glasser, The Aim and Methods of Assessment of Medical Technologies, Tekmed Congress, 1987, Lyon, France.

Institute of Social and Preventive Medicine, University of Lausanne (Switzerland) Seminars on: Meta Analysis in Health Care Research, and The Role of Statistics and Epidemiology in Environmental and Occupational Health (1986)

Methods of Analysis for Populations Exposed to Environmental Health Hazards, California State University, San Diego (1986)

John Lawson, and Jay H. Glasser, "Analysis and Profile Methods for Child Survivorship Research". Invited paper: American Public Health Meetings, 1986.

Health Profiles for Hazard Waste Disposal and Hazard Waste Incineration Operations. A series of profiles for monitoring the health of populations potentially exposed to environment contaminants around hazardous waste site impoundments or incinerator operations. State of Missouri (1981-1986).

Overview of Analytic Issues in Using The National Center for Health Statistics Public Use Tapes, the National Center for Health Statistics Data Tape Users Conference. Summer, 1986

Miscellaneous Publications: (Continued)

Use of Secondary Data in Health Statistics Analysis, National Center for Health Statistics Data Tape Users Conference. Summer 1984.

Health Profiles for Hazardous Waste Site Monitoring Data Use Conference on Small Area Statistics, National Center for Health Statistics. Summer 1984.

Westinghouse, Public Applied Systems: "Population and Family Planning: Data, Analyzing and Management Decision Applications" (March 1983).

Statistics Section, American Public Health Association, Lowell Reed Invited Lecture. Annual Meetings (November 1983).

UNITED STATES DISTRICT COURT
Western District of Washington at Tacoma

No. C83-74TB

LYNN ANNETTE HILL, et al.,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTTICALS, INC., et al.,
Defendants.

Deposition of JAY H. GLASSER, a witness of lawful age, taken on behalf of counsel for the Plaintiffs in the above-entitled matter, pursuant to notice, before Shirley D. Jones, Notary Public, at the law offices of Paulson, Nace & Norwind, 1814 N Street, N.W., Washington, D.C., commencing at 12:27 p.m., Thursday, March 3, 1988.

APPEARANCES:

BARRY J. NACE, Attorney-at-Law
Paulson, Nace & Norwind
1814 N Street, N.W.
Washington, D.C. 20036
Counsel for Plaintiffs

FRANK C. WOODSIDE III, M.D., Attorney-at-Law
Dinsmore & Shohl
2100 Fountain Square Plaza
511 Walnut Street
Cincinnati, Ohio 45202-3172
Counsel for Defendants

APPEARANCES (cont.)

ROBERT L. DICKSON, Attorney-at-Law
Haight, Dickson, Brown & Bonesteel
201 Santa Monica Boulevard
P. O. Box 680
Santa Monica, CA 90406
Counsel for Defendants

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Q. Doctor, when one looks at these three limb reduction studies, considering the relative risks that are developed there, and considering the various problems or limitations within the studies themselves that you talked about, using your experience, your education, and your training with respect to public health, epidemiology, biostatistics, and biometry, putting all that together in your area that you have worked in all these years, looking at those three studies that, in some respect, involve the limbs, would you be able to come up with an opinion within a reasonable degree of epidemiological certainty as to whether or not there is a statistical association between Bendectin and limb defects?

A. Well, I had concluded that, in a preponderance of all the data in the studies, that there is --

MR. WOODSIDE: I object to the question. Does he have an opinion?

BY MR. NACE:

Q. First of all, do you have an opinion?

A. Yes.

Q. What is that opinion?

A. My opinion is that in the preponderance of these studies, I believe the weight of them is that there is an association.

* * *

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there has been no foundation from either an epidemiologic or other scientific standpoint for him to give such an opinion, and because it includes birth defects other than those which are the subject matter of this litigation.

BY MR. NACE:

Q. You may answer.

A. I believe that there is an association between -- from the sum and substance of the literature that I reviewed and from my point of expertise, that it has an association of Bendectin with congenital disorders.

MR. WOODSIDE: I move to strike.

BY MR. NACE:

Q. Doctor, have you previously been qualified in federal courts in this country to give testimony with respect to Bendectin?

MR. WOODSIDE: Objection. It is an irrelevant consideration in questioning.

THE WITNESS: Yes.

BY MR. NACE:

Q. Do you recall where those courts were?

A. In Kansas City, Missouri and in Tyler, Texas.

Q. Finally, I have one more series. I am going to show you -- You may have seen this exhibit, 441 for identification.

* * *

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Bendectin, do you?

A. No, I do not.

Q. You do not have any publications that deal with the components of Bendectin, such as doxylamine; correct?

A. Correct.

Q. You have never published any articles in the peer reviewed literature dealing with antihistamines, have you?

A. No.

Q. Nor with anti-nauseants or anti-emetics; correct?

A. Correct.

Q. In addition, you have never published any articles in the peer reviewed literature dealing with birth defects; correct?

A. Well, no.

Q. When you say no, you mean, yes, I'm correct, you have not published any?

A. No. I have published some work on death certificates, which contain information. But that is not a major area of my expertise.

Q. You have not published any articles in the medical literature dealing with teratology, embryology, or pharmacology; have you?

A. Correct.

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Q. You don't consider yourself to be an expert in those areas, do you, sir?

A. No.

Q. You have not made any presentations of a scientific nature before any professional or scientific groups dealing with Bendectin and/or its components, have you?

A. No.

Q. You have not performed any epidemiologic studies on Bendectin or its components, have you?

A. No.

Q. You have done no original studies of an epidemiologic nature with respect to birth defects, correct?

A. Correct.

Q. You have done no case control studies on illnesses or birth defects, correct?

A. On illnesses and birth defects?

Q. On illnesses or birth defects, case control.

A. I have participated in case control studies.

Q. On illnesses or birth defects?

A. On illnesses.

Q. What kind of illnesses have you performed case control studies on?

A. I've looked at a series of cases in the National Eye

* * *

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A. Yes.

Q. And there is the epidemiology area?

A. Yes.

Q. You are the convener in the biometry area, correct?

A. Yes.

Q. You are not in the epidemiology area, correct?

MR. NACE: I have to object. What do you mean by "in"? I don't understand the word.

BY MR. WOODSIDE:

Q. Do you have an appointment in the epidemiology area?

A. No. Currently, we can have only one appointment in one of the disciplines.

Q. So that your appointment is in the biometry discipline, as opposed to the epidemiology discipline; correct?

A. Correct.

MR. WOODSIDE: Be off the record for just a second here. I have got to find something here.

(The deposition was briefly suspended in place.)

BY MR. WOODSIDE:

Q. You do not consider yourself to be an expert in epidemiology, do you, sir?

A. No. As I have explained in the past, I believe that my expertise is in biometry, with a secondary application in

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epidemiology.

Q. Just so I'm clear, the answer to my question was no; correct?

MR. NACE: I object. The answer is what you got.

BY MR. WOODSIDE:

Q. Was the answer to my question no?

A. I tried to give you a complete answer to your question.

Q. Sir, do you recall that you gave testimony in Kansas City, Missouri on December 7, 1987 in a case styled Barbara Susan Rudell and others v. Merrell Dow Pharaceuticals, Inc?

A. Yes, I do.

Q. Sir, do you recall that on that occasion, you were asked the following question and gave the following answers: "Okay. Now, you do not consider yourself to be an expert in epidemiology, do you, sir?" Answer: "No." Sir, do you recall that question and that answer?

A. Yes, I do.

Q. Sir, you were under oath at that time; were you not?

A. Yes.

Q. And you told the truth; did you not, sir?

A. I did not finish my sentence.

Q. Did you tell the truth?

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A. Yes.

Q. Thank you. Sir, do you recall a case styled David A. Barton and Tamara T. Barton v. Richardson Merrell, Inc.? Sir, do you remember that your deposition was taken on September 2nd and 3rd, 1987 in a case called David A. Barton and Tamara T. Barton v. Richardson Merrell, Inc.?

A. Yes.

Q. Do you recall, sir, on that occasion that you were asked the following question and gave the following answer: "Do

you consider yourself or do you put yourself out as an expert in epidemiology?" Answer: "No, not as -- no, no, I do not." Did you give that testimony on that occasion, sir?

A. As I recall, yes.

Q. Did you tell the truth at that time, sir?

A. Yes.

Q. Are you familiar with an organization known as ACT or the Association of Consulting Toxicologists?

A. Yes. I am familiar with something called the Association of Consulting Toxicologists.

Q. Sir, that is an organization which makes arrangements for individuals to testify on occasion; correct?

A. I understand that's part of what they do.

Q. In some instances, they basically obtain witnesses to

* * *

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necessary, Mr. Nace, I will be glad to demonstrate that.

MR. NACE: Absolutely.

BY MR. WOODSIDE:

Q. I would like to ask you a number of questions about your opinion testimony that you have given in this particular case. First of all, it is true, is it not, that there is no epidemiology study looking at limb defects in humans where the authors conclude there is a statistically significant association between the ingestion of Bendectin and limb reduction defects in the offspring; correct?

A. Correct.

Q. I believe you indicated that you had read or reviewed a number of epidemiology studies relating to Bendectin. Correct?

A. Correct.

Q. And I believe you indicated that some of those studies were better than others. Is that a fair statement?

A. Correct.

Q. But you did, in fact, consider all of the studies for whatever value they may have been.

A. Yes.

Q. There is, in fact, an epidemiological or biostatistical technique known as pooling or metaanalysis;

* * *

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the same as a cause and effect relationship. Correct?

A. Correct.

Q. Epidemiologic studies are designed to determine whether there is or is not an association; correct?

A. Correct.

Q. Even if one gets an association in an epidemiologic study, that does not mean that there is a cause and effect relationship; correct?

A. Correct.

MR. NACE: Wait a minute. I object. Do you mean automatically? I don't understand your question. Always, automatically, or generally?

MR. WOODSIDE: I'll expand upon the question.

BY MR. WOODSIDE:

Q. The mere fact that in an epidemiologic study there is a statistically significant association does not mean, without more, that there is a cause and effect relationship; correct?

A. Well, again, I think one needs to look at exactly what it is one is trying to accomplish. In a clinical trial, which is a prospective cohort study, we may have set up hypotheses to be tested in advance that would give a cause and effect inference in the sense of the polio myelitis example. That was set up as a prospective cohort study, randomized populations

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among the treatment and control group, and then tested for the significant protective effect of the Salk polio trial.

Now, in that sense, I would say that was looking towards a cause and effect relationship. With a case control study, we are looking more towards the association aspect.

Q. In the Bendectin studies which you reviewed, there were case control and cohort studies; correct?

A. But no clinical trials.

Q. That's where we going, okay?

A. Correct.

Q. I'll get back to the clinical trials question in a minute.

A. I didn't mean to anticipate your line of questioning.

Q. That's quite all right. Let me ask the question again, and you'll see where I'm going. In the Bendectin studies that you reviewed, there were both case control and cohort studies; correct?

A. Correct.

Q. In those studies that you reviewed, there were no

controlled clinical trials; correct?

A. Correct.

Q. In the studies that you reviewed, they were trying to determine whether there was an association or not between

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Bendectin exposure and the development of birth defects; correct?

A. Correct.

Q. In those studies, they were not attempting to determine whether, based upon the studies alone, there was a cause and effect relationship; correct?

A. Well, again, there is a difference between the statistics and the design and the conclusions or inference that various authors drew. So, again, there is not necessarily "statistics", and that's it. It was the interpretation that various people placed on them that was also in the literature.

Q. In those studies that you have referred to on Bendectin, that is, both the case control and the cohort studies, none of the authors concluded in their studies that Bendectin caused birth defects; did they?

A. Correct.

Q. Let me ask you a question about controlled clinical trials for a minute. Did I use the right term?

A. That's fine.

Q. That the term you used a minute ago?

A. (Nodding head up and down.)

Q. Have you ever seen or reviewed any controlled clinical trials on Bendectin?

* * *

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limb defects in which the relative risk is increased and the confidence intervals do not include 1?

A. When you say "published articles," do you mean the article in the Journal of the American Medical Association?

Q. Let me go back and make sure my question is correct.

MR. NACE: I'm going to object. I think a simple answer -- You can answer his question. He asked about J-A-M-A, JAMA.

MR. WOODSIDE: You'll see where I'm going.

BY MR. WOODSIDE:

Q. You indicated in your direct testimony that you

reviewed a number of publications dealing with Bendectin and limb reduction defects which appeared in peer reviewed scientific or medical journals; correct?

A. Correct; and also associated reports or background documents, though.

Q. I'll get to that in a minute.

A. Okay.

Q. For the purpose of my question that I'm now asking you, I want to limit the scope of my question to those articles which have been published in peer reviewed medical or scientific journals, okay?

A. Okay.

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Q. I will get to the other things in a minute, I assure you. Directing your attention again to the concept of evidence of association as it appears on that chart, I have the following questions. It is true, is it not, that there are no epidemiologic studies published in the peer reviewed medical or scientific literature looking at limb reduction defects in which there was evidence of an association between the Bendectin exposure and limb reduction defects?

A. Oh, no. I would say there are many articles that indicate evidence of it, but in the sense that I would use that word.

Q. Today, in this litigation, you have referred to "evidence of association" in putting materials on the board in relating and referring to the Mitchell article; correct?

A. Correct.

Q. For the purposes of this question, I am utilizing the terms "evidence of an association" the way Dr. Mitchell and others used it and the way you used it when you referred to their article and explained certain epidemiologic techniques, okay?

A. Okay.

Q. In the epidemiology studies looking at limb reduction defects and Bendectin that have been published in peer

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reviewed, refereed, scientific or medical journals, there are none in which there is evidence of an association as utilized in the Jicks -- excuse me -- as utilized in the Mitchell article about which you have testified on your direct examination?

MR. NACE: I'm going to object. You can tell us

what articles you are referring to.

MR. WOODSIDE: Any.

MR. NACE: Well, you imply that there are many that were done, Mr. Woodside. What are you referring to? How many were done?

MR. WOODSIDE: He came in and gave a bunch of testimony. I want to know if in the articles that he reviewed he found any dealing with epidemiology studies looking at limb reduction defects and Bendectin that have been published in the literature that he has reviewed.

MR. NACE: I object to that as being an unfair question. You are asking a negative question that presupposes that there must be a negative answer. Improper.

MR. WOODSIDE: The question is perfectly acceptable.

MR. NACE: No, I think it is not acceptable. I think it is phrased in such a way -- It is one of those questions that is designed solely to get an answer that will satisfy you

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but not necessarily be accurate and lead to the truth of the matter.

BY MR. WOODSIDE:

Q. Doctor, can you answer my question?

A. Well, I'm trying to distinguish two things that you are asking about in this sense versus the metaanalysis sense that you were asking about before. So, you are confining yourself to the --

Q. To the individual articles.

A. No. There are no individual articles that flatly come out and conclude that there is an evidence of association in the sense that it is written -- given up there, as its total and final conclusion.

Q. As it relates to limb reduction defects, there are no epidemiologic studies published in the peer reviewed scientific literature dealing with Bendectin in which there is an elevated relative risk and the 95 percent confidence intervals do not include one; correct?

MR. NACE: I object to the relevancy of that question.

MR. WOODSIDE: Fine.

BY MR. WOODSIDE:

Q. Can you answer my question?

A. No.

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Q. Meaning, no, I am correct, there are no such studies?

A. You are correct.

Q. In those epidemiologic studies where there is an increased relative risk but the confidence intervals include 1, you have indicated that the result is inconclusive; correct?

A. Correct, for a given -- right; any one given confidence interval.

Q. Right; in any one given study?

A. I mean, that's part of the problem I'm having with answering your question because each of these articles, as we have gone over, have many different confidence intervals looking at different conditions. And that's where I have -- There is no one article that has one confidence interval. It often has many different confidence intervals looking at many different aspects. So, the difficulty that I'm having -- and I'm going to try to answer as precisely and clearly as possible -- is that the thrust of what you seem to be saying is as though there was one confidence interval within one article, and that is it.

Q. I don't believe I asked that question. I was referring to the confidence intervals in studies that same way you were when you were referring to Dr. Mitchell's article and writing things on the board, or whatever you call this thing.

* * *

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A. Correct.

Q. Sir, this study deals with oral clefts; correct?

A. Correct.

Q. You do not know when you would have to administer a substance during gestation for it to cause oral cleft, do you?

A. No.

Q. So that you don't know if the administration of a drug at the end of the eighth or ninth weeks would be too late to cause a birth defect of this type or not, do you?

A. Correct.

Q. Would you turn for just one minute to Plaintiffs' Exhibit 519, which is the study by Rothman and others entitled "Exogenous Hormones and Other Drug Exposures of Children with Congenital Heart Disease." In particular, if you would refer to Table 1, please.

A. (Examining) Yes, sir.

Q. I believe you had referred to that table during your direct examination. Correct?

A. Correct.

Q. I believe, in particular, you looked at the line dealing with doxylamine succinate, dicyclomine hydrochloride, and pyridoxine hydrochloride. Correct?

A. Correct.

* * *

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MR. NACE: Your objection is certainly noted.

BY MR. NACE:

Q. Doctor, let me move on to the McCredie article. You made some reference to the editorial comments of McCredie. What did you mean by that?

A. Well, when I had opened it up -- again, we have been asking about, I as the reviewer, or a peer reviewer, or what I would think that any peer reviewer would ask about. When I saw the title of the article, I was taken aback by it, frankly, "The Innocent Bystander," because that's not usual parlance in any refereed scientific article, as opposed to an editorial, because it is an editorial opinion.

And one of the things that concerned me in the text of it, and I would be affected -- and, I think, again, I would leave it to any reviewer, peer reviewer or not -- that when a scientific article begins by talking about the litigation and that parents -- a quote in the first paragraphs -- "Parents and their lawyers are preparing further lawsuits for some legal opinion," "accepts a list of women who took the drug," and goes on in that nature, that it has already set up a kind of editorial climate. So, I did try, then, after that, of course, to disregard the opening paragraph but did not find the closing paragraph as any surprise.

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MR. WOODSIDE: Objection. Move to strike.

BY MR. NACE:

Q. Is this the kind of language that one usually sees in objective reporting by researchers in the field of epidemiology?

MR. WOODSIDE: Objection.

THE WITNESS: Absolutely not. And it con[trasts] strikingly to the measured language that we have been talking about in most -- of all of this literature that we have reviewed

today.

BY MR. NACE:

Q. This person, McCredie, would you look down at the bottom of the first column. It says, "Janet McCredie, MD, Associate Professor of Radiology." Is there anything in the that article that suggests that McCredie is an epidemiologist, a statistician, a biostatistician?

A. No, there is not.

Q. You made a comment about the article being dispassionate," to use the word that you used. What did you mean by that, and how were you using that word?

A. Well, I think I meant that it seemed to me offputting, far from dispassionate in its introduction and the circumstances in which you try to set up a measured, and

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learned, and objective study to report in a journal, particularly a medical journal.

Q. Were you aware, sir, that Janet McCredie had been listed as an expert witness on behalf of Defendant Merrell?

A. No.

MR. WOODSIDE: Objection.

BY MR. NACE:

Q. Were you aware, sir, that when I attempted to take her deposition --

MR. WOODSIDE: Mr. Nace --

MR. NACE: You wanted to bring up the article by McCredie. We'll bring it up.

MR. WOODSIDE: No, no, no. You brought it up.

MR. NACE: That's right. I'm sure you're going to bring it up in your case, too.

BY MR. NACE:

Q. When I attempted to take the deposition of Dr. McCredie, that she was withdrawn as an expert, and we weren't able to get her deposition?

MR. WOODSIDE: Objection.

THE WITNESS: I have no knowledge of that.

BY MR. NACE:

Q. Let's go to the Aselton article now. If you look down

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at the bottom of the first page, the right-hand column, I think you'll see the name of John B. Chewning, Merrell Dow Pharmaceuticals.

A. Yes.

MR. WOODSIDE: It says "Dr. John B. Chewning" on it.

MR. NACE: It does say "Dr. John B. Chewning, Merrell Dow Pharmaceuticals," who, as I understand it, is also a member of the legal department of the company .

BY MR. NACE:

Q. Do you see that, that he also contributed to this article?

A. They are acknowledging his contribution.

Q. And Dr. Jick is also one of those authors; is that correct?

A. Correct; second author.

Q. Doctor, you had some comment that you wanted to make about this article that you asked to make, and Mr. Woodside objected at the time. What comments did you want to make?

MR. WOODSIDE: I object. That's irrelevant, immaterial, inappropriate, improper.

MR. NACE: I know those are rote objections. But I don't think they are appropriate.

MR. WOODSIDE: They are not rote.

* * *

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conditions. So, metaanalysis, really looking at the way it is used, is really a collection or a view towards aggregating results.

Q. How about pooling?

A. And pooling is often used -- Again, in discourse, some people use the words interchangeably. Some are like Alice in Wonderland: The words are what I say they are. But then there also are very specific statistical techniques that refer to pooling, like when can you put together very different, very precisely defined strata, or stratified analysis. So, I think there has been some rather general and unfortunate use of these phrases.

Q. Why wouldn't you do it in this case?

A. Because here, there is no consistent methodology. That's the problem. Certainly, we would all agree, from the variety of articles that we have reviewed, the techniques, the different populations studied, cohort, case control, if we look

at different risk factors that were considered in some studies, smoking, spermicide, not in other studies, all of these say there is not that kind of uniformity to these studies.

Q. Doctor, you were asked about some Association of Consulting Toxicologists. You are not a toxicologist?

A. No.

UNITED STATES DISTRICT COURT
Western District of Washington at Tacoma

No. C83-74TB

LYNN ANNETTE HILL, et al.,

Plaintiffs,

v.

MERRELL DOW PHARMACEUTTICALS, INC., et al.,

Defendants.

Deposition of JAY H. GLASSER, a witness of lawful age, taken on behalf of counsel for the Plaintiffs in the above-entitled matter, pursuant to notice, before Shirley D. Jones, Notary Public, at the law offices of Paulson, Nace & Norwind, 1814 N Street, N.W., Washington, D.C., commencing at 12:27 p.m., Thursday, March 3, 1988.

APPEARANCES:

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[11]
societies that I have belonged to.

Q. Have you held any elected positions in those organizations?

A. Yes, I have.

Q. What would they be?

A. Most recently just a few of them: I was the head of the Social Statistics Section of the American Statistical Association, which that section had some 6,000 members in it as part of the American Statistical Association. I have just completed my duties as the chair of the Statistics Section of the American Public Health Association. And, among other things, I have held several positions as far as grant review committees for national government and similar assignments. Currently, I will be working for the United Nations in an assignment abroad.

Q. I want to ask you about two things, the grant review and also the assignment abroad. What is the assignment abroad that you are talking about?

A. This one that's coming up which, unfortunately, had precluded, if I may mention, my attendance at the trial in Seattle, is to serve for the UN as an expert advisor. This particular project is a six to eight-week first assignment in Pakistan to help them plan a national health interview survey
[12]
and a health examination survey of the entire population of Pakistan. I quickly add, when I say "entire population," meaning that a sample will be drawn from across Pakistan, and people will be asked to come in, interviewed about their health conditions, their health problems, diet, nutritional status, disease states, and also concurrently have a physical and medical exam to look at the medical and clinical aspects of the

problem.

My role in that is three-fold, as I understand it. One is to help analyze some prior, past small studies they have done in preparation to this national survey; secondly, to help them plan the full field implementation, that is to say, the full study itself; and then, thirdly, to help in the training of their personnel. In that sense, I will be giving -- designing and giving several courses which, as we discussed before, include elements of both biometry, epidemiology, and demography, demography being the study of population and distribution of people.

Q. This is through the United Nations?

A. Yes.

Q. How long do you expect to be gone out of the country for that?

A. This will -- The initial assignment, because there may **[13]**
be subsequent ones, will be six to eight weeks.

Q. You mentioned grants. What is your relationship to grants?

A. Well, I have served and am serving as a reviewer for grants. The United States Government, when it gives monies to researchers, calls for those people who are applying to send in research grants. And that's in the way we spoke of before about research design. There would be a protocol for carrying out the study. In order to review these, because these are competitive grants, they call upon what is called peer review. That is that people like myself and others who are working in the cognizant and related fields to review these grants fairly and objectively, to look at both the scientific merit, kind of practical doability, and the possible significance and application of results that would come from these. Through this process of ranking these competitive grants, the awardees are chosen, because usually there are far more applications that come in for the amount of money that's available for these research projects.

Q. Have you also served as a peer reviewer?

A. Yes, I have.

Q. Maybe I'll ask you, first of all -- because we don't know exactly when this tape will be shown. So, what is a peer **[14]**
reviewer?

A. A peer reviewer is where you call upon someone who has commensurate experience and commensurate knowledge to either look at a grant proposal, a research proposal or, in the case of scientific publications and what are are called refereed journals, would be asked to review the submitted article for its validity, reliability, and contribution to the field. So, I have served both as a grant reviewer on research grants, as well as a peer reviewer for journals.

Q. Would you tell us what some of those journals are that you have been a peer reviewer for.

A. The ones that I currently have manuscripts to review, a task that I need to complete before leaving, are the New York State Journal of Medicine, Medical Care, and the American Journal of Public Health.

Q. Have you served in any national or international committees with respect to areas that might be involved with epidemiology?

A. Yes.

Q. Would you tell us what some of those would be.

A. For several years, I have served on committees for the National Center for Health Services Research and Health Care Technology. I have also just served as the chair of a review

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ever been appointed by a court to do epidemiological analysis?

MR. WOODSIDE: Objection.

MR. NACE: Go ahead.

THE WITNESS: Yes, I have. Recently, I have served as the expert appointed by a court in Richmond, the federal bankruptcy court, in the Dalkon Shield, Robins Dalkon Shield IUD, that is, the intrauterine device litigation that is before the court, which is located in Richmond, Virginia.

BY MR. NACE:

Q. Doctor, let me now try to get to the areas of the relative risk, statistical significance, and that sort of thing. We have over here behind you a board and a new, black Markette pen. . If you feel it is appropriate, I would ask you to use the board at any time. First of all, with respect to relative risk, what is a relative risk as far as epidemiology is concerned

A. I think it would be useful to put some things on the

board. Relative risk, which we can abbreviate as RR, is a concept that is used to appraise the risk of an outcome among an exposed population, where we mean by "exposed population" -- and I'll abbreviate that with POP, with an N, for population. In other words, a group of people who may be exposed to something that we believe -- a drug, a device, or other -- that

* * *

11. Affidavit of John Davis Palmer, Ph.D., M.D. and curriculum vitae (Dock. No. 186), filed Sept. 28, 1989

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UNITED STATES DISTRICT COURT
Southern District of California

No. 84-2013-G(I)

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardian Ad Litem for JASON DAUBERT, a Minor,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50 Inclusive,
Defendants.

NO. 84-2929-G(I)

MICHAEL SCHULLER, ANITA DE YOUNG, and ANITA DE YOUNG as Guardian ad Litem for ERIC SCHULLER,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50., Inclusive
Defendants.

[2] **AFFIDAVIT OF JOHN PALMER, M.D.**

1. My name is John Palmer. I am a physician licensed to practice medicine in Arizona, California, and Minnesota. I am a full professor at the Department of Pharmacology, college of Medicine, University of Arizona, Tucson. I received my Bachelor of Science in pharmacy and my Masters in pharmacology from the University of Colorado. I received my Ph.D from the University of Minnesota in pharmacology 1961 and my medical degree from the University of Minnesota in 1962. A copy of my curriculum vitae is attached.

I have served as associate professor of pharmacology and full professor of pharmacology at the University of Arizona. I have also earned a special post-doctoral fellowship; served as a visiting scientist and visiting clinical pharmacologist at the Cardiovascular Research Institute at University of California Medical Center; and have been a visiting lecturer at the University of California, Berkeley where I was also a visiting professor of pharmacology. I have been a visiting scientist and lecturer at the University of Washington School of Medicine, Department of Internal Medicine. I have been a visiting professor of pharmacology at the University of Colorado

Medical Center; a clinical associate professor of medicine at the University of Washington [Boise, Idaho words added by JP] Veterans Administration Hospital; Director of St. Lukes/[V letter added by JP]AMC in Boise, Idaho; [internship word added by JP] held a volunteer position at the Rocky Mountain
[3]
Biological Laboratory; and I have had a major interest in medical education and basic pharmacology.

I have received fellowships from the American Foundation for Pharmaceutical Education, USPHS Combined MD/PhD Training Program, and the USPHR Special Post Doctoral Fellowship. I have received awards for superior scholarship at the University of Colorado, was elected as the outstanding lecturer at the Colorado School of Medicine, and selected to the Dean's List of Excellence in Teaching of Basic Sciences. I have had numerous grants for research and I have served on numerous committees involved with medicine. I have taught Pharmacology, Internal Medicine, Preparation for Clinical Medicine, Clinical Pharmacology of Cardiovascular Drugs, Fluids and Electrolytes, Psychopharmacology, Applied Pharmacology, etc. I have served as a consultant to several Veterans' Administration Hospitals, the Charles F. Kittering Foundation in Denver, Colorado, the National Institutes of Health, and am a member of the American Society for Clinical Pharmacology and Therapeutics, American Society of Pharmacology and Experimental Therapeutics, the American Association for the Advancement of Science, the Western Pharmacology Society, the American Foundation for Clinical Research, etc. I have published approximately 22 articles in scientific journals subject to referee and review, published approximately 7 book chapters and had numerous abstracts published and presented.
[4]

As a pharmacologist I have naturally also had an interest in the actions of drugs and chemicals on the human body and cells. I have performed and have been responsible for animal studies involving drugs. These studies involve determining the

toxic effects of drugs.

2. In teaching pharmacology the subsections that are taught as part of the pharmacology curriculum include toxicology and the subsection of teratology. By virtue of my education, training and experience, I am familiar with the principles and general methodology utilized in determining whether of not a drug is toxic to cells in the humans and have in fact done such research. When one examines whether or not a chemical or drug effects the cells of an fetus one is examining the toxic effects of the substance, a pharmacologic function.

3. I have reviewed various pieces of scientific data and literature pertaining to Bendectin. I have specifically reviewed what I believe to be all of the animal studies pertaining to Bendectin. These include the studies performed by the company bearing the titles 63-01; 63-02; 63-27; 63-28; 63-29; 66-01; 66-02; 66-05; 66-07; 67-12; 75-12; and 75-13.

I have also reviewed original data collected on Bendectin performed by the company that appeared in notebooks 401-T and 458-T. I have also examined reports generated by the manufacturer of Bendectin on animal studies involving drugs other than Bendectin including Thalidomide, Clomid, etc. I

[5]

have further reviewed animal studies that were conducted by research institutions outside the premises of Richardson Merrell. These include studies that are know as the "Roll" studies; the Research Triangle Institute Study; Studies by Hendrickx; Studies by McClure; and others.

I have further reviewed in vitro studies that have been performed pertaining to Bendectin and its component doxylamine succinate. These include studies by the following authors or organizations: Hassell and Horrigan; Budroe; Guntakatta; Crescitelli; and BGA.

I have also examined pharmacological data pertaining to Bendectin and doxylamine succinate. These include various pharmacological articles that I have previously been examined upon in my deposition, which have been provided to the defendant and include Slikker, Holder, Ganes, Scott, and

others.

4. Company data concerning adverse reaction reports, case reports, and other such memoranda are also generally and reasonably relied upon to help determine teratogenicity.

5. I have further examined and reviewed the epidemiological data pertaining to Bendectin. In my opinion, the pharmacological data, the animal studies data, the in vitro studies data, the epidemiological data, and other human data are all, jointly viewed by those who are trying to determine whether or not a drug, such as Bendectin, is teratogenic, although the epidemiological data is the least

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reliable.

6. A component of Bendectin was doxylamine succinate, an antihistamine. It is what is known as a type H_1 class and is clearly associated with Benadryl. It is both a lipophilic and hydrophilic substance and is thereby by definition an antipathic substance. It is moreover of a low molecular weight and is accepted as being able to pass through the placenta and reach the cells of the human fetus.

7. It is my opinion within a reasonable degree of certainty that the pharmacology data shows that Bendectin and specifically its component doxylamine succinate, has teratogenic properties.

8. The animal studies that have been performed show results that found heart defects, reduced fetal size, diaphragmatic hernias, reduced ossification centers (bone composition), sternal defects, limb defects, etc. In fact, the RTI studies produced data that found that there was less than 1 in 1000 chance that Bendectin did not cause ossification defects.

9. It is my opinion within a reasonable degree of certainty that the animal studies performed by the company and those performed by other organizations shows that Bendectin and specifically its component doxylamine succinate, has teratogenic properties.

10. The in vitro studies performed show that Bendectin and doxylamine succinate affected the process of
[7]
chondrogenesis, interfered with DNA synthesis, caused chromosomal breakage and the like.

11. It is my opinion within a reasonable degree of certainty that the in vitro studies performed on Bendectin and its component doxylamine succinate shows that Bendectin and specifically its component doxylamine succinate, has teratogenic properties.

12. It is my opinion within a reasonable degree of certainty that the epidemiological data, company memoranda, case reports, and other human data shows that Bendectin and specifically its component doxylamine succinate, has teratogenic properties.

13. When looking at the evidence in total, it is my opinion within a reasonable degree of medical and scientific certainty that Bendectin is a teratogen and specifically is capable of causing birth defects and limb defects in the human being when ingested at the normal therapeutic dose at the time that the cells of the body are developing and creating numerous structures, including the limbs.

14. I have also examined the medical records pertaining to the Daubert and Schuller children and it is my opinion within a reasonable degree of medical certainty that in each case the drug Bendectin was taken at the period of time such as to effect the cells that would produce the normal limb structure and that Bendectin did cause the limb defects in each of the children.

/s/
John Palmer

Acknowledged before me on this 22nd day of September, 1989.
My Commission Expires: August 15, 1993

/s/
Judy K. Smith, Notary Public

CURRICULUM VITAE

JOHN DAVIS PALMER, Ph.D., M.D.
Department of Pharmacology
College of Medicine
University of Arizona
Tucson, Arizona 85724

June 15, 1987

BIRTH:
Sterling, Illinois
October 31, 1931

EDUCATION:
University of New Mexico, 1949-1951
University of Colorado, 1951-1955, B.S. Pharmacy, M.S. Pharmacology
University of Minnesota, 1955-1962, Ph.D., Pharmacology, 1961; M.S., 1962
Thesis: The Treatment of Experimental Acute Hemorrhagic Hypotension with Mixtures of Pressor Amines.
Director: R.N. Bieter, Ph.D., M.D.

POSITIONS:
Research Assistant, University of Colorado, College of Pharmacy, 1954-55.
Teaching Assistant - Pharmacology, University of Minnesota Medical School, 1955-58.
Fellow, American Foundation for Pharmaceutical Education, 1955-58.
Fellow, USPHS/NIH combined MD/PhD Training Program, 1959-62.
Intern, Internal Medicine, University of Minnesota Hospitals, 1962-63.
Special Postdoctoral Fellow, USPHS/NIH, 1963; awarded but never activated.

Assistant Professor of Pharmacology, University of Colorado Medical Center, 1963-66.
Director, Multidiscipline Laboratories, University of Arizona, College of Medicine, 1966-86.
Associate Professor of Pharmacology, University of Arizona, College of Medicine, 1969-present.
Resident (part-time), Department of Internal Medicine, University of Arizona, College of Medicine, 1972-73, Board Eligible.
Assistant Professor, Internal Medicine (Clinical Pharmacology) University of Arizona, College of Medicine, 1973-present.
Visiting Scientist (Clinical Pharmacology) Cardiovascular Research Institute, University of California Medical Center, San Francisco, July 1973-December 1973 (sabbatical leave).
Visiting Lecturer, University of California, Berkeley, 1973 1980.
Visiting Professor of Pharmacology, University of California, Berkeley, 1975, 1981-present.
Physician-Rotator, Sage Memorial hospital, Navajo National Health Foundation, Ganado, AZ, September, 1983.
Visiting Scientist, Lecturer, University of Washington School of Medicine, Department of Internal Medicine, Veterans Administration Medical Center, Boise, Idaho, 1984-85, sabbatical leave.
Visiting Professor of Pharmacology, University of Colorado Medical Center, Denver,colorado, October 1985, October 1986, February 1987, and October 1987.
Clinical Associate Professor of Medicine, University of Washington Veterans Administration Hospital, Boise, Idaho, January 1986 through December 1986.
Director, St. Luke's/VMAC, Boise, Idaho, Preliminary Year Internal Medicine Residency, 1986.
Volunteer Physician, Rocky Mountain Biological Laboratory, Gothic, Colorado, Summer, 1986, 1987 and 1988.

Professor of Pharmacology, university of Arizona, college of Medicine, 1988.

MEDICAL LICENSURE AND CERTIFICATION:

Minnesota, 1963, Examination
Arizona, 1971, Reciprocity
California, 1973, Examination/Reciprocity
American Board of Internal Medicine - Eligible

MAJOR INTEREST/SPECIALIZATION:

Medical Education
Basic Pharmacology
Cardiovascular
Antibiotics and Chemotherapy
Shock
Clinical Pharmacology
Rational use of drugs in humans
Drugs for the elderly

FELLOWSHIPS AWARDS AND GRANTS:

Fellowships:

American Foundation for Pharmaceutical Education, 1955-58.
USPHS Combined MD/PhD Training Program, 1959-62.
USPHS Special Postdoctoral Fellowship, 1963, awarded but not activated.

Awards:

Cited for Superior Scholarship, University of Colorado, 1954
Dean's List for Excellence in Teaching of Basic Sciences.
Committee on Faculty Tenure and Promotion, Chairman, temporarily then member, College,
Selected as Outstanding Lecturer (small group leader) University of Colorado School of Medicine, Fall Quarter, 1985 and 1986.

Grants:

Principal Investigator:

Effect of Endotoxin on Vascular Control Mechanisms, NIH 1964-67 and GRS, University of Colorado, 1954-65.

Vascular Changes Associated With the Development of Cardiogenic Shock, American Heart Association, 1966-68.

Neutralization of Endotoxin by Antibiotics, GRS 1970-72.

Neutralization of Endotoxin by Antibiotics, Arizona Heart Association, 1970, sponsorship of Summer medical Student Research (two students).

Effect of Glucocorticoids on Cardiovascular Function, American Heart Association, 1970-72.

A Model of IgE Induced Pathophysiology Following Aerosol Antigen Challenge BRS, 1977-79, with Dr. M. Halonen.

Effect of Glucocorticoids on Vascular Reactivity. UpJohn, 1978-1981.

Co-Principal Invetigator:

IgE Induced Cardiovascualr Pulmonary Alterations with R.N. Pinckard, Ph.D. Arizona Heart Association, 6/1/73-5/31/75.

Collaborating Investigator:

Diagnosis and Characterization of Myocardial Infarction with R.N. Pinckard, Ph.D., NHIL, 7/01/71-6/30/74.

Factors Controlling Humoral Antibody Synthesis with R.N. Pinckard, Ph.D., NIAID, 7/01/71-6/30/77/

Intensive Surveillance of Drug User in and Inpatient Population of a Hospital General Medical Ward : th R. Bressler, M.D., FDA contract, 7/01/73-6/30/77.

Clinical Pharmacology Research Training Grant, with R. Bressler, M.S., NIH 1975-present.

Pulmonary and Circulatory Alterations Induced by IgE with M. Halonen, Ph.D., PHS, 12/01/77-11/30/91, HL22582, $77,681.

Autonomic Alterations in IgE Producing Rabbits, with M. Halonen, Ph.D., and H. Yamamura, Ph.D., PHS, 12/01/83-11/30/86, HL31219.

Myocardial Damage and Fibrinolytic Agents, with J. Corrigan, M.D. and H. Allen, M.D., Arizona Heart Association and BRSG, 1982-1983.

Effects of IgG on IgE Induced Allergic Reactions with M. Halonen, Ph.D., Arizona Lung Association, 7/01/77-6/30/78.

Development and Evaluation of Instrument Systems for Non-invasive Detection, Characterization and Quantification of Atherosclerotic Lesions. I: Development of New X-ray Contrast Media, with Drs. T. Ovitt, D. Carter and S,. Nundleman. HF72931, 9/77-9/80.

Molecular Pathology of PAFs, Subgrant to University of Arizona with R.N. Pinckard, Ph.D., University of Texas at San Antonio and M. Halonen, Ph.D., University of Arizona. 4/01/78-3/31/91.

COMMITTEES:

Admissions Committee, Chairman, College of Medicine, 1966-69 and Member, 1978-81.

Group on Student Affairs, Association of American Medical Colleges, Member, National and Regional, 1966-69.

Association of American Medical Colleges, Committee on Financial Assistance to Medical Students, Member, National, 1968-69.

Committee on Human Research, Medical Referee Panel, Member, University.

Human Subjects Committee, Member, University, 1972-76.

Committee on Scholarships and Awards, Member,

University, 1968-70.
Financial Assistance Committee, Chairman, College, 1968-69.
Academic Policy and Procedures Committee, Member, College, 1968-69.
Minority Groups in Health Sciences, Member, College, 1968-75.
Interim Curriculum Committee, Member, College, 1968-69.
Pharmacology Search Committee, Member, College, 1968-70.
Ad Hoc committee on Audiovisual Services, Chairman, College, 1969-70.
Exhibits Committee, US-Mexico Border Public Health Association, Member, International,
Medical Education Review Committee, Physical Education Branch, Division of Health Professions Education, National Institutes of Health DHEW, Member, National, 1971-73.
Pharmacy and Therapeutics Committee, Veterans Administration Hospital, Member, 1966-present, Chairman, 1974-1976. Arizona Medical Center, Member 1971-present, Chairman, 1975-1984.
Ad Hoc Advisory Committee to Curriculum Committee, Member, College, 1974-75.
Preparation for Clinical Medicine, Member, College, 1975-77.
Committee on Graduate Study, Member, University 1976-78.
Clinical Research Unit Advisory Committee, 1977-1981. 81.
Phase III Electives, Member, College of Medicine, 1978-80.
Nominating Committee, Member, College of Medicine, 1981-84; Chairman, 1983-1984.
Education and Professional Training Committee, Long-Term Care Gerontology Center, University of Arizona, 1981-1986.

Committee on Geriatrics, College of Medicine, 1980-1986.

TEACHING RESPONSIBILITIES:

Pharmacology 501/801, Course Coordinator, 1968-1970 and 1976-present. Sections taught: Cardiovascular, Antibiotics and Chemotherapy, Alcohol, General Principles, Anticoagulants and Vitamins, 1968-present. 120 hours, 120 medical and graduate students. Course elected as the Outstanding Basic Science Course, 1981, 1983, and 1986.
Internal Medicine 503, Basic Clerkship, 1974-present. Ward attending, 2-3 months per year, plus 3-4 months per year on the Geriatric Assessment Unit.
Preparation for Clinical Medicine, Physical Diagnosis, 1 semester per year, 1975-present.
Phase III Electives, Clinical Pharmacology of Cardiovascular Drugs, Fluids and Electrolytes, and Clinical Pharmacology Clerkship, 1973-present.
POOL 654, Psychopharmacology. Clinical Use of the Major Psychopharmacologic Drugs. 2 hours, 50 students, 1983.
POOL 372. Applied Pharmacology. Antibiotics, 6 hours, 100 nursing students, 1983.
POOL 554. Cardiovascular Pharmacology, Antihypertensive Drugs and Antiarrhythmic Drugs, 3 hours, 10 graduate students, 1979-present.
Core Curriculum for Psychiatry Residents, Alcohol, 3 hours, 5 residents, 1986.
POOL 208. University of California - Berkeley, Course Director, 1975 and 1981-present.

CONSULTATION:

Veterans Administration Hospital, Denver, Colorado, 1964-66.
Veterans Administration Hospital, Tucson, Arizona, 1966-present.
Charles F. Kettering Foundation, Denver, Colorado, 1967.
Bureau of Health Manpower Education, Division of Physician and Health Professions Education, Department of Health, Education and Welfare, National Professions Education, Department of Health Education and Welfare, National Institutes of Health, Bethesda, Maryland, 1971.
Department of Health, Education and Welfare, Region IX, Bureau of Health Resources Development, 1973-79.
Department of Health, Education and Welfare, Health Resources Administration, Bureau of Health Manpower, 1978-79, Financial Distress Review and AHEC Review.
PHS, Health Resources Administration, Bureau of Health Professions, 1980-81.
Gibson-Stephens Neuropharmaceuticals, 1984.

MEMBERSHIPS:

American Society for Clinical Pharmacology and Therapeutics.
American Society for Pharmacology and Experimental Therapeutics, by election.
American Association for Advancement of Science, fellow, by election.
Western Pharmacology Society.
Health Sciences Communication Association.
Association of Directors of Multidiscipline Laboratories.
American Federation for Clinical Research.

SUPERVISION OF GRADUATE STUDY:

David B. Bell, University of Colorado School of Medicine, Ph.D., M.D., Director, Private Practice of Pediatrics.
V. Gene Erwin, University of Colorado School of Medicine, Ph.D., Committee Member, Dean, University of Colorado, College of Pharmacy.
Richard J. Kraemer, University of Colorado School of Medicine, Ph.D., Committee Member, Associate Professor of Pharmacology and Assistant Dean, University of Colorado, College of Pharmacy.
Marilyn Halonen, University of Arizona, College of Medicine, Ph.D., (Microbiology) Committee Member, Associate Professor, University of Arizona College of Medicine.
Sheldon Schuester, University of Arizona, College of Medicine, Ph.D., (Biochemistry), Committee Member, Faculty, University of Nebraska School of Medicine.
Aniko Meng, University of Arizona, College of Medicine, Ph.D. (Microbiology), 1978.
Anthony F. O'Malley, M.D., University of Arizona, College of Medicine, Committee Member, Ph.D., Candidate, (Pharmacology).
Sally Betz, Ph.D., (Microbiology), 1978.
Michael Wandell, Pharm. D., Postdoctoral Fellow, Clinical Pharmacology, 1980.
William Banner, M.D., Ph.D., Pharmacology, Committee Member, 1981.
Cindy Blackwell, M.S., (Toxicology), 1983.
Steven Fischer, Predoctoral Student, Microbiology, Committee Member.
J. Womble, Ph.D., Pharmacology, Committee Member, 1981.
Anne Weisse, M.S., Toxicology.
Leslie Sebring, Pharmacology, Committee Member, Ph.D., 1986.

PUBLICATIONS:

Articles in Scientific Journals
Subject to Referee Review:

Palmer, J.D., and Bieter, R.N. The treatment of experimental acute hemorrhagic hypotension with mixtures of pressor amines. Minn. Med. Bull. 33:301, 1962.

Bernstein, E.F., Palmer, J.D., Aaberg, T.A. and Davis, R.L. Studies on the toxicity of hypaque-90 percent, following rapid intravenous injection. Radiol. 76:88, 1961.

Rifkind, D. and Palmer, J.D. Neutralization of endotoxin toxicity in chick embryos by antibiotics. J. Bact. 92:815, 1967.

Palmer, J.D. Multidiscipline Laboratories. Arizona Medicine. 24:820, 1967.

Pinckard, R.N., Olson, M.S., O'Rourke, R., Palmer, J.D., Kelley, R.E. and Goldfein, S. Development of complement-fixing 19S, antiheart mitochondria autoantibody, following myocardial infarction in dogs. Circ. Res. 29:276, 1971.

Palmer, J.D., Olson, M.S., O'Rourke, R.A., Pinckard, R.N. and Goldfein, S. Experimental myocardial infarction. American Heart J. 81:729, 1971.

Pinckard, R.N., Olson, M.S., Kelley, R.E., DeHeer, D.H., Palmer, J.D., O'Rourke, R.A. and Goldfein, S. Antibody-independent activation of human C1 after interaction with heart subcellular membranes. J. Immunology 110:1376, 1973.

Palmer, J.D. and Bressler, R. Drug-Drug Interactions. Contemporary Ob/Gyn. 2(3):86, 1974 (by invitation).

Palmer, J.D., and Rifkind, D. Neutralization of the Hemodynamic Effects of Endotoxin by Polymyxin B. Surgery. Gynecology & Obstetrics 138:755, 1974.

Palmer, J.D., Pinckard, R.N., Halonen, M., Butler, C. and O'Rourke, R.A. IgE Induced Cardiopulmonary Changes in the Conscious Adult Rabbit (submitted for publication).

Pinckard, R.N., Halonen, M., Palmer, J.D., Butler, C., Shaw, J. and Henson, P.M. Intravascular Aggregation and Pulmonary Sequestration of Platelets During IgE-Induced Systemic Anaphylaxis in the Rabbit. Abrogation of Lethal Anaphylaxis by Platelet Depletion. J. of Immunology. 119"2185, 1977.

Palmer, J.D. Clinical Uses of Warfarin. Drug Therapy, 11"119, 1981.

Halonen, M., Palmer, J.D., Lohman, I.C., McManus, L.M. and Pinckard, R.N. Respiratory and Circulatory Alterations Induced by Acetyl Glyceryl Ether Phosphorycholine (AGEPC), A Mediator of IgE Anaphylaxis in the Rabbit. Am. Rev. Resp. Dis. 122:915, 1980.

Halonen, M., Palmer, J.D., Lohman, I.C., McManus, L.M. and Pinckard, R.N. Differential Effects of Platelet Depletion on the Physiologic Alterations of IgE Anaphylaxis and Acetyl Glyceryl Ether Phosphorylcholine Infusion in the Rabbit. Am Rev. Resp. Dis. 124:416-421, 1981.

Nugent, C.A., Palmer, J.D., and Ursprung, J.J. Guanadrel Sulfate Compared with Methyl-dopa for Mild and Moderate Hypertension. Pharmacotherapy 2:378. 1982.

Palmer, J.D., Nugent, C.A. Guanadrel Sulfate: A Postganglionic Sympathetic Inhibitor for the Treatment of Mild to Moderate Hypertension. Pharmacotherapy, 3:220-229, 1983.

Palmer, J.D., Clinical Pharmacology and CNS Effects of Guanadrel Sulfate and the Major Classes of Anti-hypertensive Agents. Health Science Review 1:5-7, 1984.

Smith, P.F., Palmer, J.D., Homes, T. and Halonen, M. The Responsiveness of Rabbit Bronchial Rings to Antigen. Immunopharm. 12:89-96, 1986.

Bloom, J., Baumgartner-Folkerts, C., Palmer, J., Yamamura, H., and Halonen, M., A Muscarmic Receptor Subtype Modulates Vagally Stimulated Bronchial Contraction. J. Appl. Physiol., 1988, in press.

Book Chapters:

Bressler, R. and Palmer, J.D. Drug Interaction in Aging. In: Drug Issues in Geropsychiatry, pp. 49-60. Edited by Fann, W.E. and Maddox, G.L., Baltimore, MD, Williams and Wilkins, 1974.

Palmer, J.D. A medical educator looks at pharmacy in the future. American Association of Colleges of Pharmacy and National Associations of Boards of Pharmacy Dist. 8, Proceedings of the 26th Annual Meeting. p.17, 1967 (by invitation).

Palmer, J.D. Drug Therapy for the Elderly. Bressler, R. and Conrad, K. Eds. Mosby, 1982. (Therapy for Cardiovascular Disorders and Anticoagulant Drugs.)

Palmer, J.D. and Conrad, K.A. Cardiovascular Drugs and the Management of Heart Disease. Ewy. G. and Bressler, R. Eds. Raven, 1982. Anticoagulant Drugs.

Griffith, W. Complete Reference to Prescription and Non-Prescription Drugs. Technical Consultants, John D. Palmer and William Jones. H.P. Books, Tucson, Arizona, 1983.

Palmer, J.D. and Conrad, K.A. Current Cardiovascular Drug Therapy. Ewy, G. and Bressler, R. Eds. Raven 1984. Anticoagulant Drugs: Heparin and Warfarin.

Abstracts Published and Presented:

Rifkind, D. and Palmer, J.D. The Neutralization of Endotoxin by Antibiotics Bactl. Proc. April, 1966. Am. Society for Microbiology.

Palmer, J.D. Effect of Phenoxybenzamine on the Reactivity of Resistance and Capacitance Vessels During Endotoxin Shock. Pharmacologist 8:173, 1966.

Palmer, J.D., Rifkind, D., Beauchamp, R. and Cotner, R. Neutralization of the Hemodynamic Effects of Endotoxin by Polymyxin B. Pharmacologist 13:299, 1971.

Palmer, J.D., Pinckard, R.N., Halonen, M., O'Rourke, R.A. and Butler, C. Anaphylactic Shock Related to Acute Pulmonary Hypertension. American Heart Association Meeting, November, 1975. Circ. 52(2):88, 1975.

Halonen, M., Palmer, J.D., Butler, C., Henson, P.M. and Pinckard, R.N. Role of the Platelet in IgE-Induced Systemic Anaphylaxis in the Rabbit. Fed. Proc. 36:1329, 1977.

Halonen, M., Smith, P., Holmes, T., Cutcher, A., and Palmer, J. Contraction of Rabbit Bronchial Rings to Antigen, Acetyl Glyceralether Phosphorylcholine and Histamine. Submitted, FASEB (ASBC/AAI) 1984.

Baumgartener, C., Bloom, J.W., Yamamura, H.I., Palmer, J.D., and Halonen, M. Pirenzepine Preferentially Inhibits Bronchial Contraction Induced by Pre- vs. Post-ganglionic Parasympathetic Nerve Stimulation. Submitted, American Thoracic Society, December, 1986.

Halonen, M., Baumgartener, C., Bloom, J.W., Palmer, J.D., and Yamamura, H.I. Effects of Histamine on Neuronally Induced Contraction of Rabbit Mainstem Bronchus. Submitted, American Thoracic Society, December, 1986.

Dunn, A.M., Palmer, J.D. and Halonen, M. A Search for the Mediators Responsible for Antigen-Induced Contraction of Peripheral Lung Strips (PLS) from IgE-producing Rabbits. Submitted, American Thoracic Society, December, 1986. -

Palmer, J.D., Halonen, M.J., Blackwell, C.L. In Vitro Characterization of Vascular Smooth Muscle Responses and Mediators in Rabbit IgE Anaphylasis.

Dunn, A.M., Palmer, J.D. and Halonen, M.J. Platelet Activating Factor (PAF) and Histamine Mediate Antigen-Induced Contraction of Rabbit Peripheral Lung Strips. Submitted, FASEB (AAI), December, 1987.

Palmer, J.D., Blackwell-Dyke, C., Wiese, A.J.C. and Halonen, M.J. In Vitro Characterization of Mediators Causing Pulmonary Artery Constriction in Rabbit IgE Anaphylasis. Submitted, FASEB (ASPET), December 1987.

Quan, S.F., Baumgartener-Folkerts, C., Trombley, J., Sobonya, R.E., Halonen, M.J. and Palmer, J.D. Influence of Airway Epithelium Removal on the Relationship Between in Vivo and In Vitro Histamine Responsiveness in Rabbits. Submitted, FASEB (ASPET), December, 1987.

Halonen, J., Dunn, A.M., Palmer, J.D. and McManus, L.M. An Anatomic Basis for the Species Difference in Responses of Guinea Pig and Rabbit Peripheral Lung Strips to Platelet Activating Factor. Submitted, American Thoracic Society, November, 1987.

Halonen, M., Baumgartener-Folkerts, C., Palmer, J.D. and Bloom, J.W. Airway Responsiveness to Methacholine in IgE-Producing Rabbits. To be presented, American Academy of Allergy and Immunology, March, 1988.

Abstracts Published:

Palmer, J.D. Effect of Endotoxin Shock on Mechanisms Regulations Net Transcapillary Fluid Exchange. Clin. Res. 14:128, 1966.

Bell, D.B. and Palmer, J.D. Peripheral Vascular Changes Associated with Experimental Coronary Embolization. Circ. 34(3):53, 1966.

Palmer, J.D. Effect of Endotoxin on Mechanisms Regulating Net Transcapillary Fluid Exchange. European Conf. on Microcirculation, 4th, 1966, p.47. Abstracts ..(Cambridge, 1966) 134P.

Pinckard, R.N., Olson, M.S., O'Rourke, R.A., Palmer, J.D. and Goldfein, S. Mitochondrial Autoantibody Induced by Myocardial Infarction. Clinical Research 19:118, 1971.

O'Rourke, R.A., Pinckard, R.N., Olson, M.S., Palmer, J.D. and Goldfein, S. Myocardial Autoantibody Due to Myocardial Injury. American J. Cardiology 26:652, 1970.

Pinckard, R.N., Olson, M.S., DeHeer, D.H., O'Rourke, R.A., Palmer, J.D. and Goldfein, S. Identification of a heat-labile, IgM Anti-Heart Mitochondria Autoantibody in Human Sera. Fed. Proc. 31:658, 1972.

Palmer, J.D., Pinckard, R.N., Halonen, M., Butler, C. and O'Rourke, R.A. IgE Induced Cardiopulmonary Changes in the Conscious Adult Rabbit. Clin. Res. 23:83A, 1975.

Halonen, M., Palmer, J.D., Butler, C., Henson, P.M. and Pinckard, R.N. Role of the Platelet in IgE Induced Systematic Anaphylaxis. Fed. Proc. 36:1329, 1977.

Halonen, M., Stanfield, M. and Palmer, J.D. Role of Histamine in IgE Induced Systemic Anaphylaxis in the Rabbit. Fed. Proc. 38:1415, 1978.

Halonen, M., Palmer, J.D., Lohman, I.C., Hanahan, D.J. and Pinckard, R.N. Cardiovascular and Respiratory Alterations Induced by Acetylglycerol Ether Mediator (AGEM) in Platelet Depleted Rabbits. Fed. Proc. 39:905, 1980.

12. Excerpts from "Reproductive Health Hazards in the Workplace, Congress of the United States, Office of Technology Assessment (Ex. 43 to Pltfs.' Opp. to Summ. Judg.), filed Aug. 28, 1989

Reproductive Health Hazards in the Workplace

OTA Reports are the principal documentation of formal assessment projects. These projects are approved in advance by the Technology Assessment Board. At the conclusion of a project. The Board has the opportunity to review the report, but its release does not necessarily imply endorsement of the results by the Board or its individual members.

CONGRESS OF THE UNITED STATES
[SEAL] Office of Technology Assessment
Washington, D.C.

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Toxicology Studies

Toxicology studies include in vitro and whole animal tests of suspected hazards that allow the investigator to examine the roles of dose and routes of exposure. While extrapolation to humans is a complicated task, these studies, properly executed and interpreted can *predict* an association with agents to which humans are exposed, in contrast to epidemiology studies in which the humans will already have been affected by exposure to the hazard.

Although evidence from studies on humans is often used to refute or confirm results from animal screening tests, toxicology studies are necessary for several reasons (20):

- Experimental studies that deliberately expose humans to potentially toxic chemicals are ethically unacceptable, except in special circumstances (e.g., clinical trials for new pharmaceuticals) where there is extensive evidence from animal studies and informed consent has been given.
- Epidemiological studies of workers exposed to a chemical already in production, or reports of adverse reactions to substances, are available for only a small number of chemicals (see chapter 4).
- Even in epidemiological studies of exposed humans, results are difficult to interpret because of factors such as the lack of large enough samples and good exposure data, difficulty in measuring endpoints, and confounding variables.
- Although epidemiological studies are variable, tests on animals have proven to be an important source of data on human risk.

* * *

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A basic tenet of toxicology is that effects observed in experimental animals can be used to infer likely effects (or lack of effects) in humans, with appropriate consideration of biological differences between species. And, in general animal models do have good predictive value for humans (see chapter 4). For example, in reproductive toxicology studies, substances that affect menstrual cycles in monkeys and estrous cycles in rodents also affect menstrual cycles in humans (tables 6-4 and 6-5). Effects on fertility in rodents also seem to be a good indicator of effects in

humans; most of the original work on contraceptive agents was carried out on rodents (1). However, interpreting effects of toxic doses on sexual behavior and pregnancy from animals to humans is far more complex. There are so many differences in sexual behavior between humans and animals that special care must be exercised not to misinterpret results.

Selection of the proper species is extremely important because one or even more species may give "false negative" results. The experience with Thalidomide is a case in point. Effects similar to the phocomelic-type limb deformity observed in humans were observed in a few breeds of rabbits and several species of primates. Thalidomide has been tested in 10 strain of rats, 15 strains of mice, 11 breeds of rabbits, 2 breeds of dogs, 3 strains of hamsters, 8 species of primates, and in cats, armadillos, guinea pigs, swine and ferrets. Developmental effects were only occasionally produced in any of these species. However, there were fertility effects: prenatal mortality was high in rabbits, and there was a low conception rate in rats (20). This underscores the importance of selecting the appropriate species examining other endpoints as indicators of toxic effects, and of performing human epidemiology studies to corroborate the information from animal studies.

Table 6-4 — Selected Examples of Reproductive Toxic Effects Common to Animals and Humans

Compound	Effect in animals	Effect in humans
Benzene	Estrous cycle disturbance, rat	Menstrual disorders
Styrene	Estrous cycle disturbance, rat	Menstrual disorders
Chlordecone (Kepone)	Testicular atrophy, decreased fertility, mouse, rat, rabbit, both sexes, females more affected	Decreased sperm count and motility, abnormal morphology
Chloroprene	Testicular damage, decreased sperm count, dominant lethal mutations, mouse, rat, cat	Decreased libido, impotence, decreased sperm count, motility, abnormal morphology, increased spontaneous abortion in wives
DBCP	Testicular atrophy, decreased fertility, dominant lethal mutations, rat, rabbit, guinea pig	Testicular atrophy, decreased sperm count, decreased fertility
Arsenic	Embryolethal, teratogenic, mouse, hamster, rat	Low birth weight, spontaneous abortions
Carbon monoxide	Fetotoxic, low birth weight, poor postnatal development and brain damage, rodent, rabbit, sheep, pig, monkey	Fetotoxic, low birth weight, fetal brain damage
PCB	Low birth weight, high perinatal and postnatal mortality, poor postnatal growth, skin discoloration, mouse, rat, rabbit, pig, dog, monkey Prolonged estrous cycle, rat Prolonged menstrual cycle, donkey Spontaneous abortion, rhesus monkey	Low birth weight, high postnatal mortality, skin discoloration Menstrual disorders
Lead	Wide spectrum of effects, rats and mice, both sexes	Wide spectrum, both sexes
EDB	Sterility, rats, bulls	Reduced fertility in men
Carbon disulfide	Effects on spermatogenesis, rats Early embryonic mortality — increased congenital malformations, rat	Sperm abnormalities Spontaneous abortions, women

[illegible] Chemical Hazards to Human Reproduction (Park Ridge, NJ: Noyes Data Corp., 1983), p. 184.

BEST AVAILABLE COPY

13. "Report on the Safety of Bendectin/Diclectin for Use in the Management of Nausea and Vomiting of Pregnancy," dated Aug. 11, 1989 (submitted in support of Merrell Dow's Reply to Affidavits of Pltfs.' Experts Submitted in Opp. to Deft.'s Mot. for Summ. Judg.), filed Oct. 3, 1989

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MERREL DOW PHARMACEUTICALS INC.

UNITED STATES DISTRICT COURT
For the Southern District of California

NO. 84-2013-G(I)

WILLIAM DAUBERT; JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, a minor,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES 1 through 50, Inclusive,
Defendants.

NO. 84-2929-G(I)

MICHAEL SCHULLER, ANITA DE YOUNG, and ANITA DE YOUNG as Guardian Ad Litem for ERIC SCHULLER,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC., and DOES
1 through 50, Inclusive

Defendants.

DEFENDANT'S REPLY TO AFFIDAVITS OF PLAINTIFFS' EXPERTS SUBMITTED IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

REPORT ON THE SAFETY OF BENDECTIN/DICLECTIN FOR USE IN THE MANAGEMENT OF NAUSEA AND VOMITING OF PREGNANCY

Prepared by a panel of consultants in teratology for the Special Advisory Committee on Reproductive Physiology to the Health Protection Branch.

11 August 1989

INTRODUCTION

Diclectin is the only drug product on the Canadian market that is indicated specifically for the management of nausea and vomiting of pregnancy. It contains the same active ingredients as Bendectin. Bendectin was marketed for many years worldwide by Merrell Dow.

Recently, controversy regarding alleged association of Diclectin with birth defects has been raised in the Canadian parliament. The Minister of Health and Welfare Canada has requested an independent review by an expert panel. The following report is respectfully submitted.

REPORT

The evaluation of Bendectin (doxylamine succinate; pyridoxine hydrochloride) teratogenicity has included extensive human

epidemiological studies, whole animal studies, and in vitro studies involving several methods. There has been no prescription drug that has been more extensively studied for reproductive toxicity. After considering five parameters for evaluating teratogenicity, it can be concluded that the prescribing of Bendectin to a human population presents no measurable reproductive risks to that population. These parameters include:

1. Human epidemiological studies evaluating the association of birth defects and Bendectin exposure.

2. Evaluating the changing incidence of birth defects with changing use of Bendectin (secular trend data).

3. Animal test results.

4. Dose-response relationship of animal tests.

5. Biological plausibility.

Controlled studies involving over 130,000 patients have not demonstrated any reproducible or consistent association of birth defects with Bendectin exposure. In fact, the results of the epidemiological studies are just what one might expect of an agent without reproductive or teratogenic risks.

Secular trend data from several sources do not support an association between Bendectin exposure and the incidence of birth defects. The frequencies of the limb reduction defects (LRD) and congenital heart disease (CHD), specifically, are not correlated with Bendectin exposure; after withdrawal of the use of Bendectin in the United States, there was no decrease in their rates of occurrence.

Animal studies in primates (Hendrickx et al, 1985) and extensive studies in rats sponsored by the U.S. Food and Drug Administration (Tyl et al, 1988) demonstrate the lack of teratogenicity of Bendectin at many times the human therapeutic dose. There are no peer reviewed or responsibly performed studies that demonstrate a teratogenic effect of Bendectin in any animal species.

Of course, a dose-response relationship is not present in animal models since teratogenicity is not produced in the pharmacological range in which the drug is used.

The allegation of teratogenicity is not supported by in vitro studies that have tested doxylamine at doses above the levels reached in humans receiving therapeutic doses of Bendectin. These investigations have examined the toxicity of doxylamine using mutagenesis testing and toxicity in various cell culture systems. Furthermore, after more than thirty million women have been treated for nausea and vomiting of pregnancy and after numerous studies to evaluate the reproductive effects of Bendectin, there is no indication that there is a spectrum of malformations associated with Bendectin exposure - a so-called Bendectin Syndrome - as there is with all other proven human teratogens.

This analysis allows us to conclude that Bendectin presents no measurable reproductive risk.

In recent years, methods for assessing the combined outcome of a number of related studies have been developed. This methodology, termed meta-analysis, has been applied to the human studies regarding Bendectin. The meta-analysis of the pooled results of 17 trials indicates no statistically significant relationship between maternal Bendectin exposure during the first trimester of pregnancy and subsequent fetal abnormalities (Einarson et al, 1988).

There is a high incidence of birth defects in the general population, even in those women who take no drugs. Bendectin has not altered this incidence. The meta-analysis yields an odds ratio of 1.01 with a 95% confidence interval of 0.66 to 1.55. This means that the range of possibilities for the risk of congenital malformation associated with exposure to Bendectin is between two-thirds and one-and-one-half times the risk of malformation that occurs in the general population. When a confidence interval includes unity, it indicates no increased risk.

After consideration of the relevant data, the panel submits the following recommendations in response to the Minister's questions.

Q1. Given available date, is there evidence that exposure to Bendectin/Diclectin during pregnancy increases the risk of congenital malformations in the offspring?

A. No. Numerous studies in animals and in humans that have been reported in the scientific and medical literature demonstrate that Bendectin is not a teratogen. A compound that has no teratogenic effect can be expected, solely on the basis of chance, to be associated with congenital malformations if it is used widely by pregnant women. The types of congenital malformations reported will vary considerably, not following a consistent pattern of birth defects. The safety of Bendectin/Diclectin in the management of nausea and vomiting of pregnancy has been established by its use in many thousands of pregnant women. The types and numbers of abnormal offspring born to these women were in no way different from those that would be expected to occur in a similar group of women who did not take these drugs during pregnancy. The panel believes that the risks of Bendectin have been grossly misrepresented to the public.

Q2. Does Bendectin/Diclectin serve a useful role in the management of nausea and vomiting of pregnancy?

A. Yes. These drugs were the only ones for which sufficient evidence of safety and effectiveness in the management of nausea and vomiting of pregnancy was submitted to drug regulatory bodies in Canada and abroad, thereby allowing this claim to be made. No other drugs have been nearly so well investigated for this purpose. It must be emphasized that Bendectin was never banned from sale in any country. It was withdrawn from the market worldwide in 1983 by the manufacturer who found the legal costs of defending its use (successfully in the majority of cases) to be prohibitive.

There has been an unfortunate consequence of this withdrawal for pregnant women. For example, in the United States, the number of women being admitted to

hospital suffering from severe nausea and vomiting of pregnancy has increased two-fold.

Q3. Does the benefit [t]o risk assessment of Diclectin indicate that it should be removed from sale in Canada?

A. No, for the reasons cited above. It would be a disservice to Canadian women to withdraw this drug from the market.

Q4. If the answer to question three is no, what restrictions, if any, should be placed on the sale of Diclectin? Are any changes needed in the physician or patient labelling?

A. There should be no restrictions placed on the availability of Diclectin in Canada. It should be indicated for the management of nausea and vomiting of pregnancy without the qualifications which exist at present. The panel believes that there is an overemphasis on cautionary statements in the current labelling for Diclectin, which is not reflected in recent studies that have been reported in the medical and scientific literature. The labelling should be modified accordingly.

REFERENCES

1. Hendrickx AG, Cukierski M, Prahalada S, Janos G, Booher S, and Nyland, T: Evaluation of Bendectin embryotoxicity in nonhuman primates: II. Double-blind study in term cynomolgus monkeys. Teratology 32:191-194, 1985.

2. Tyl RW, Price CJ, Marr MC, and Kimmel CA: Developmental toxicity evaluation of Bendectin in CD rats. Teratology 37:539-552, 1988.

3. Einarson TR, Leeder JS, and Koren G: A method for meta-analysis of epidemiological studies. Drug Intelligence and Clinical Pharmacy 22:813-824, 1988.

4. Biringer A: Antinauseants in pregnancy: teratogens or not? Canadian Family Physician 30:2123-2125, 1984.

PANEL

Dr. Robert L. Brent, Philadelphia, Pennsylvania
Dr. Gideon Koren, Toronto, Ontario
Dr. Anthony Scialli, Washington, D.C.
Dr. Ernest Zimmerman, Cincinnati, Ohio

REPRESENTATIVE FROM THE HEALTH PROTECTION BRANCH

Dr. Michele Brill-Edwards (Chair for the Panel)

REPRESENTATIVES FROM THE SPECIAL ADVISORY COMMITTEE ON REPRODUCTIVE PHYSIOLOGY

Dr. Jack H. Walters (Chairman of the Committee)
Dr. Carl E. Boyd (HPB) (Executive Secretary of the Committee)

APPENDIX TO THE REPORT ON THE SAFETY OF BENDECTIN/DICLECTIN FOR USE IN THE MANAGEMENT OF NAUSEA AND VOMITING OF PREGNANCY

CURRICULA VITAE OF THE EXPERT PANEL

Dr. Robert Brent (to follow)
Dr. Gideon Koren (to follow)
Dr. Anthony Scialli
Dr. Ernest Zimmerman

REFERENCE PAPERS CITED IN THE REPORT OF THE PANEL

1. Hendrickx AG, Cukierski M, Prahalada S, Janos G, Booher S, and Nyland, T: Evaluation of Bendectin embryotoxicity in nonhuman primates: II. Double-blind study in term cynomolgus monkeys. Teratology 32:191-194, 1985

2. Tyl RW, Price CJ, Marr MC, and Kimmel CA: Developmental toxicity evaluation of Bendectin in CD rats. Teratology 37:539-552, 1988.

3. Einarson TR, Leeder JS, and Koren G: A method for meta-analysis of epidemiological studies. Drug Intelligence and Clinical Pharmacy 22:813-824, 1988.

4. Biringer A: Antinauseants in pregnancy: teratogens or not? Canadian Family Physician 30:2123-2125, 1984.

PRODUCT MONOGRAPH (LABELLING) FOR DICLECTIN

Doxylamine succinate is an antihistaminic with anticholinergic and sedative properties. Antihistaminics are competing with histamine for the receptors of the effective cells. Pyridoxine HCl is a nutrient also called vitamin B_6

Toxicology: The oral LD50 of doxylamine is 470 mg/kg in the mouse and 250 mg/kg in the rabbit. The oral and sub-cutaneous LD50 of pyridoxine HCl are respectively 5500 and 3700 mg/kg in the rat.

For additional information on pregnancy and animal studies, see "PRECAUTIONS".

PRODUCT MONOGRAPH

DICLECTIN

An association of Doxylamine succinate -- Pyridoxine hydrochloride

Antinauseant
against nausea and vomiting
of pregnancy

Laboratorie Duchesnay
Laval, Quebec
(514) 668-9750
820014

DATE OF PREPARATION:
October 25, 1983

Action: The action of Diclectin is due to two unrelated compounds. Doxylamine succinate, an antihistaminic, provides the antinauseant and antiemetic activity; pyridoxine HCl provides a supplement of vitamin B_6 to prevent a possible pyridoxine deficiency during pregnancy. Also, studies have shown that pyridoxine could have an antinauseant activity. The antiemetic activity of Diclectin is delayed by a special coating of the tablet, a dose taken at night will be effective in the morning, the time mostly needed.

Indications: Diclectin is indicated only in cases of nausea and vomiting which are not relieved by traditional approaches (ingestion of salted biscuits or hot or cold liquids), and only when the symptoms interfere with normal alimentation or daily activities and are of sufficient severity to require medication (See Precautions-pregnancy).

PRECAUTIONS: **Pregnancy**

a) Animal studies

Teratogenecity studies of Diclectin or of its two active ingredients (doxylamine succinate and pyridoxine HCl) were done in different animal species: Sprague-Dawley rats, New-Zeland or Holland rabbits, NMRI mice, rhesus monkeys (*M. mulatta)* and cynomolgus (*M. fascicularis)*. The studies did not show any teratogenic effects due to Diclectin or to its active ingredients. However, two uncompleted recent studies could show a potential teratogenecity of Diclectin in certain species as indicated in the following paragraphs.

Studies in Sprague-Dawley rats and New-Zeland rabbits, at doses of Diclectin 90 times the maximal human dose (MHD) did not reveal any drug-induced fetal abnormalities. In a small scale study, pregnant cynomolgus monkeys were given Diclectin (10 to 20 times the MHD) by organogenesis. Abnormalities of the cardiac intraventricular wall were observed in 4 out of 6 foetus extracted at 100 days of gestation (normal gestation period is 160 days). A 40-days aborted foetus seemed normally developed. Three other foetus at term, did not show any cardiovascular abnormalities after usual clinical examinations at birth. In some other studies where rhesus and cynomolgus monkeys were administered Diclectin for a shorter period, the foetus were normal at birth.

Doxylamine succinate given to Wistar rats and NMRI mice at doses up to 60 times the MHD and to Sprague-Dawley rats and Holland rabbits up to 125 times the MHD, did not produce congenital abnormalities. Female Wistar rats given doses 125 to 175 times the MHD had foetus with ondulated ribs (7 to 10%) and hiatal hernia (2 to 6%). A global increase in foetal resorption, from a zero to three times were also observed in most of the rodents receiving 125 or more times the MHD.

b) Epidemiological studies

Many epidemiological studies (control and cohort) were done to evaluate the teratogenecity potential of Diclectin. It is concluded from these studies that there is no association between the use of

Diclectin and the presence of congenital abnormalities. A few of these studies leave the impression that a relation exists between the use of Diclectin and a particular congenital abnormality, but the associated abnormality differs from one study to the other. These results are considered hypothetical and not conclusive for many reasons: one of them is because they are from multiple analysis of the same data (i.e. studies of many drugs and many possible abnormalities at the same time). Recent epidemiological studies seem to indicate a possible association between the drug (or the treated disease or one and the other) and a pyloric stenosis. But more importantly, a third study did not reveal any association with this pathology. In the two studies, the stenosis could have been produced by the nausea or vomiting or other factor not associated with the medication. Certain abnormalities were particularly studied in other epidemiological studies and their relation with the use of Diclectin were not confirmed. More studies are actually in progress to clarify the problem. The cohort studies were designed to detect a small increase (less than 2X) of the global rate of malformations but they were not sensitive enough to eliminate the multiplication by two of a particular malformation (ex. 1/1000 to 2/1000).

For this reason, Diclectin should be used to treat nausea and vomiting of pregnancy only for cases resisting to traditional, non medicated procedures. Doctors who have decided to use a medication to stop nausea and vomiting of pregnancy should know that more studies on the risk of congenital abnormalities were done with Diclectin than with any other antinauseant drugs (a bibliography on Diclectin is available, on request, to the practitioner). Due to a risk of drowsiness, Diclectin must be prescribed with caution to automobile drivers and machine operators. It must also be used with caution in combination with alcohol and other CNS depressing drugs or with epileptic patients.

Secondary effects: The secondary effects are those produce by the two ingredients. Doxylamine succinate may cause drowsiness, vertigo, nervousness, epigastric pain, headache, palpitation, diarrhea, disorientation, irritability, convulsions, urinary retention or insomnia. Pyridoxine is a vitamin that is

generally recognized as having no adverse effects.

Symptoms and treatment of overdose: Signs and symptoms of intoxication are restlessness, dryness of mouth, dilated pupils, sleepiness, vertigo, mental confusion and tachycardia. The treatment if needed is gastric lavage, emetics or activated charcoal and a symptomatic treatment.

Dosage: **Adults**: Two tablets at bedtime. In severe cases or when nausea occurs during the day, one additional tablet in the morning and another in midafternoon.

CONSUMERS INFORMATION
DICLECTIN

Summary: Diclectin is indicated to treat nausea and vomiting that could happen during the first weeks of pregnancy. You should take this medication only if these symptoms are interfering with your alimentation or your daily activities and if other treatments prescribed by your doctor are ineffective. Ingestion of salted biscuits or toasts or drinking of hot or cold liquids in the morning at waking are some of these treatments.

There is no method to prove that in rare cases, a substance absorbed by a pregnant woman will not cause a congenital abnormality. Consequently, no medication, including Diclectin, should be taken during pregnancy unless it is absolutely necessary.

Diclectin could cause drowsiness, so before you know its action on you, be cautious while driving a care or operating any machine.

More information on Diclectin are found in this insert. Read it and keep it for further reference.

Use of Diclectin: Nausea and vomiting at the beginning of pregnancy are frequent. They are not generally the signs of a disease and they fade away or disappear after a few weeks, without treatment. For women who can tolerate these symptoms,

the simpliest treatments are salted biscuits or toasts or drinking of hot or cold liquids in the morning at waking. If these measures are ineffective and if the symptoms are sufficiently severe to interfere with the ingestion of food or your daily activities, then medication is desirable.
Diclectin contains two pharmaceutical ingredients: an antihistaminic (doxylamine) and vitamin B_6.

How to use Diclectin: In general, nausea and vomiting of pregnancy occur in the morning. Take two tablets at bedtime so the medication could be effective in the morning. If this dose does not relieve the symptoms, you could take another tablet in midmorning or in midafternoon. Your doctor can modify the dosage based on the time of appearance and the severity of the symptoms. If you have violent nausea and vomiting and if Diclectin is ineffective, consult your doctor. If you forget to take a dose of Diclectin, take it as soon as you realized it. Take the other doses as indicated. Do not take two doses at the same time, unless duely prescribed by your doctor.

Pregnancy and congenital abnormalities: Out of one hundred newborns, two or three have a serious congenital abnormality. This risk can be increased if the mother takes certain drugs or other substances like alcohol during pregnancy. The risk of congenital abnormality is increased if the substance is taken during the first 8 to 12 weeks of pregnancy, the time period at which the main organs of the foetus are under development. It is impossible to prove that a drug or any other substance taken during pregnancy is without any risk or totally innocuous.

Many studies were done in women taking this medication during pregnancy. In most of these studies, it was not proven that Diclectin increases the risk of congenital abnormality. A few studies have shown an increased risk of abnormalities but as the same results were not obtained in other studies, we cannot conclude that the abnormalities were due to this medication. However, no study was done in a sufficient scale to eliminate the possibility of a very small increase of risk. AS IT IS NOT POSSIBLE TO PROVE THAT A MEDICATION TAKEN DURING PREGNANCY WILL NOT PRODUCE A

CONGENITAL ABNORMALITY IN RARE CASES DICLECTIN SHOULD BE TAKEN ONLY IN ABSOLUTE NECESSITY. Even if this booklet warns you on the use of Diclectin, of all the antinauseant and antivomiting drugs used during pregnancy, this drug was the most studied. There are no supporting data to prove that another drug is safer to treat nausea and vomiting of pregnancy.

Nursing mothers should know that a small quantity of drug could be ingested by the infant. We do not know if undesirable effects could be produced on the baby.

General precautions: Diclectin could cause drowsiness. As long as you do not know how you are reacting to the medication, be cautious while driving a car or operating a machine. Deeper drowsiness could be produced if Diclectin is taken in combination with alcohol or other drugs like drugs for cough or colds, antidepressives, analgesics or tranquillizers.

If you had a severe reaction to an antihistaminic or to Diclectin in the past, advise your doctor. These reactions are severe drowsiness, insomnia, hyperactivity or excitation.

Secondary effects: In addition to drowsiness, Diclectin can produce vertigo, headache, confusion, irritability, insomnia, gastric pain. If you experience some of these effects or any other effect, consult your doctor.

Other information: For Diclectin to be effective, it must be taken as recommended on the label. This drug is specifically prescribed for you and your actual state of health. Do not give it to others even if they have the same symptoms. Even for you, do not use it for any other condition than the one for which it was prescribed.

If you think that you or someone else has taken an overdose, immediately call the antipoison center, your doctor, your pharmacist or the emergency service of the nearest hospital.
KEEP THIS DRUG AND ALL OTHER DRUGS OUT OF REACH OF CHILDREN.

If you want more information on Diclectin, consult your doctor or your pharmacist. They have available a more technical document (product monograph) that you could read.

Presentation: Each white, coated, delayed release tablet contains doxylamine succinate USP 10 mg pyridoxine HCl USP 10 mg. Bottles of 100, 500 and 1000 tablets.

Chemistry and pharmacology: The chemical name of doxylamine succinate is N, N-dimethyl-2-1-phenyl-1 (2-pyrimidyl) ethoxy-butanedioate (1:1). 2-a-2(dimethylamino) ethoxy-a-methylbenzyl pyridine (1-1 ethamine succinate. It is very soluble in water and alcohol, easily soluble in chloroform and slightly soluble in ether and benzene. Its formula is the following:

[FIGURE OMITTED]

The chemical name of pyridoxine HC1 is 5-hydroxy-6-methyl-3, 4 pyridine dimethanol HC1 or pyridoxile hydrochloride. It is easily soluble in water, slightly soluble in alcohol and insoluble in ether. Its formula is the following:

[FIGURE OMITTED]

14. District Court's Memorandum Decision and Order granting summary judgment to Merrell Dow, filed Nov. 1, 1989

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT
OF CALIFORNIA

WILLIAM DAUBERT, et al., *Plaintiffs*,	)	
v.	)	
MERRELL DOW PHARMACEUTICALS, INC., et al., *Defendants*.	)	CIVIL NOS. 84-2013-G(IEG), 84-2929-G(IEG) (Consolidated)
MICHAEL SCHULLER et al., *Plaintiffs*,	)	
v.	)	
MERRELL DOW PHARMACEUTICALS, INC., et al., *Defendants*.	)	

MEMORANDUM DECISION AND ORDER

EARL B. GILLIAM, UNITED STATES DISTRICT JUDGE:

The defendant's motion for summary judgment was scheduled for hearing on October 6, 1989, in Courtroom 7 before the Honorable Earl B. Gilliam. Plaintiffs were represented by Mary Gillick and Barry Nace. George Berry, Robert Dickson and Pamela Yates appeared on behalf of defendant. Having considered the points and authorities and oral argument of counsel, the court issues this memorandum decision and order granting defendant's motion for summary judgment.

FACTS

This case involves personal injuries sustained by plaintiffs. Infant plaintiffs and their guardians ad litem seek damages from defendant for injuries (limb reduction birth defects) allegedly sustained as a result of the mothers' ingestion of Bendectin during pregnancy. Bendectin is a prescription pharmaceutical product previously manufactured by Merrell Dow, indicated solely for the treatment of nausea and vomiting during pregnancy. Defendant has moved for summary judgment, arguing that plaintiffs have failed to sustain their burden of establishing a genuine issue of material fact regarding causation.

DISCUSSION

Summary judgment is proper "after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. . . ." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "[T]h[e] standard [for granting summary judgment] mirrors the standard for a directed verdict under Federal Rule of Civil Procedure 50(a). . . ." *Id.* at 323 (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986)).

In this case the defendant has moved for summary judgment. Plaintiffs, who have the burden of proof by a preponderance of the evidence, oppose the motion. The court must therefore determine "whether a fair-minded jury could return a verdict for the plaintiff [based] on the evidence presented." *Anderson v. Liberty Lobby, Inc.* 477 U.S. at 251-252. The court must view the evidence in a light most favorable to plaintiff, however, "[t]he evidence is insufficient if the strongest inference to be drawn in the plaintiff's favor is that defendant's negligence could *possibly* have been the cause of the accident." *Bieghler v. Kleppe*, 633 F.2d 531, 533 (9th Cir. 1980) (emphasis in original) (citing *Neely v. St. Paul Fire & Marine Insurance Co.*, 584 F.2d 341, 345 (9th Cir. 1978)). The plaintiff must show that defendant's negligence "was more probably than not the proximate cause of the accident" to defeat summary judgment and take the

issue to a jury. *Bieghler* at 533. The court should exclude inadmissible evidence objected to by either party prior to ruling upon the motion. *See, Hollingsworth Solderless Terminal Co., v. Turley* 622 F.2d 1324, 1335 (9th Cir. 1980).

Federal Rule of Evidence (FRE) 703, restricts the admissibility of scientific evidence. "A necessary predicate to the admission of scientific evidence is that the principle upon which it is based 'must be sufficiently established to have general acceptance in the field to which it belongs.'" *United States v. Kilgus*, 571 F.2d 508, 510 (9th Cir. 1978). Therefore, expert opinion not based on facts or data "of a type reasonably relied upon by experts in the particular field" is not helpful, but instead is confusing or misleading and should therefore be excluded. *See*, Fed.R.Evid. 403. *See also Barrel of Fun, Inc. v. State Farm Fire and Casualty Co.*, 739 F.2d 1028, 1033 (5th Cir. 1984) (excluding expert's opinion based on polygraph test). "Whether an expert's opinion has an adequate basis, and whether without it an evidentiary burden has been met, are matters of law for the court to decide." *Richardson v. Richardson-Merrell*, 857 F.2d 823, 829 (D.C.Cir. 1988), *cert. denied*, 107 L.Ed. 2d 171 (1989).

There are two schools of thought governing expert testimony in these Bendectin cases, and one seems to be prevailing in the federal courts. Unfortunately for the plaintiffs, the prevailing school of thought warrants summary judgment in this case.

The prevailing school is best exemplified by *Brock v. Merrell Dow Pharmaceuticals*, 874 F.2d 307 (5th Cir. 1989), *modified*, 884 F.2d 166 (5th Cir. 1989), *rehr'g denied, en banc*, 884 F.2d 167 (5th Cir. 1989) where the court held the following:

> We find, in this case, the Brocks' failure to present statistically significant epidemiological proof that Bendectin causes limb reduction defects to be fatal to their case.

Id. at 313. The court also noted:

> Hopefully, our decision will have the effect of encouraging district judges faced with medical and epidemiological proof

> in subsequent toxic tort cases to be especially vigilant in scrutinizing the basis, reasoning, and statistical significance of studies presented by both sides. However, we do not wish this case to stand as a bar to future Bendectin cases in the event that new and statistically significant studies emerge which would give a jury a firmer basis on which to determine the issue of causation.

Id. at 315. Several other cases are in accord with this reasoning. *See, Richardson v. Richardson-Merrell, supra*; *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190 (1st Cir. 1987); *Hull v. Merrell Dow Pharmaceuticals, Inc.*, 700 F.Supp. 28 (S.D.Fla. 1988); *In Re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, 624 F.Supp. 1212 (S.D.Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988), *cert. denied* 109 S.Ct. 788 (1989); *Thompson v. Merrell Dow Pharmaceuticals, Inc.*, 229 N.J.Super. 230, 551 A.2d 177 (1988).

In medical cases like this one, courts must "critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to consistently and rationally resolve the disputes before them." *Brock*, 874 F.2d at 310. Absent a scientific understanding of the cause of the birth defects at issue in Bendectin cases, causation may be shown only through reliance upon epidemiological evidence. *See, Richardson v. Richardson-Merrell*; *Lynch v. Merrell-National Laboratories*. *See also In Re Agent Orange Product Liability Lit.*, 611 F.Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2nd Cir. 1987) (stating that epidemiological studies were "the only useful studies having any bearing on causation" in Agent Orange cases).

In *Richardson*, Dr. Done, the plaintiff's expert, relied upon 1) chemical structure activity analysis, 2) *in vitro* (test tube) studies, 3) *in vivo* (animal teratology) studies, and 4) reanalysis of epidemiology studies. He used the results of these four types of studies to conclude that within a reasonable degree of certainty, Bendectin causes birth defects. The court concluded that Dr. Done's testimony lacked an adequate scientific basis:

> These three types of studies -- chemical, *in vitro*, and *in vivo* -- cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. Studies of this kind singly or in combination are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence.

Richardson, 857 F.2d at 830. The court also rejected the reanalysis of the epidemiological studies:

> Dr. Done further admitted that no one who had published work on Bendectin had concluded that there was a statistically significant association between Bendectin and limb reduction defects. . . . Only by recalculating the data was Dr. Done able to obtain what he deems a statistically significant result. Moreover, the studies rejected by Dr. Done had been published in peer-reviewed scientific journals, while Dr. Done has neither published his recalculations nor offered them for review.

Id. at 831 (emphasis added).

The plaintiffs rely on *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C.App. 1986) and other cases which basically give more deference to the expert's opinion. *Oxendine* is the leading Bendectin case in this regard, and the appellate court found that Dr. Done had a sufficient foundation for his testimony when he relied upon chemical analyses, animal studies, *in vitro* studies and recalculations of epidemiological studies:

> Dr. Alan Done, appellant's sole causation witness, had testified that no conclusion about Bendectin's effect on humans could be drawn from any of the four types of scientific data upon which he principally relied when each type was considered separately from the others. The [trial] court focused on this fact and concluded that if each type of data, viewed in isolation, was not sufficient to prove that Bendectin caused birth defects, then all of them taken

> together could not prove it either. In so doing, the trial court erred [by granting defendant's motion for J.N.O.V.].

Oxendine, 506 A.2d at 1104. The *Oxendine* court viewed the recalculations of epidemiological studies and the varying conclusions as involving a "classic battle of the experts." *Id.* at 1110. The court refused to find that plaintiffs had provided insufficient evidence to support the jury verdict solely because they had not provided a single original or recalculated epidemiological study which showed a statistically significant association between Bendectin and birth defects. *Id.* at 1107-10.

Oxendine is definitely in the minority camp. Although there appears to be no Ninth Circuit authority directly applicable to these Bendectin cases, this court must view the authority developed by three other federal circuit courts in *Brock*, *Lynch* and *Richardson* as highly persuasive.

In this case, the plaintiffs offer the opinion testimony of eight experts to establish that Bendectin is a teratogen (it causes limb reduction defects generally), and that Bendectin ingested by the mothers during pregnancy caused the limb reduction defects suffered by the infant Daubert and Schuller plaintiffs. Those experts are Dr. Adrian Gross, Dr. Stuart Newman, Dr. Alan K. Done, Dr. Shanna Swan, Dr. Jay Glasser, Dr. Wayne Snodgrass, Dr. Johannes Thiersch and Dr. John Palmer. Plaintiffs have submitted this testimony in the form of affidavits, deposition transcripts, and transcripts from previous trials.

Dr. Adrian Gross is a licensed and accredited veterinarian with experience in pathology and toxicology. *Ealy v. Richardson-Merrell* transcript, Exhibit 26 at pages 650-60. Dr. Gross would testify at trial that to within a reasonable degree of certainty Bendectin is a teratogen. Dr. Gross would base his opinion on animal studies which allegedly show a statistically significant association between Bendectin and doxylamine succinate (a component of Bendectin) and birth defects. *Id.* at pages 834-38.

Dr. Stuart Newman is a specialist in developmental biology. *Ealy* transcript, Exhibit 21 at pages 198-203; *Newman Affidavit* at pages 1-6. Dr. Newman would testify at trial that to within a reasonable degree of certainty "Bendectin is capable of interfering with the development of the limb in the human being and causing birth defects in the developing limb of the human being and that Bendectin is a human teratogen in the normal therapeutic dose." *Newman Affidavit* at page 9. Dr. Newman would base his opinion on *in vitro* studies and the pharmacology aspects of Bendectin. *Id.*

Dr. Alan Done is a medical doctor with specialties in pediatrics, clinical pharmacology and toxicology. *Oxendine v. Richard-Merrell* transcript, Exhibit 31 at page 3. Dr. Done's profferred testimony is unclear from the materials presented, but he apparently would testify that to a reasonable degree of certainty Bendectin is a teratogen. *Id.* at 854. Dr. Done apparently would base his opinion on analyses of the chemical structure and properties of doxylamine succinate animal studies *in vivo, in vitro* studies, and various informal and formal human studies, including epidemiological ones. *Id.* at 853.

Dr. Shanna Swan is an epidemiologist and biostatistician practicing in the field of reproductive epidemiology. *Ealy* transcript, Exhibit 12 at pages 3523-27. Dr. Swan would testify that to a reasonable degree of certainty, it is her opinion "that considering all available data that is provided in animal, *in vitro* and epidemiological studies, including the relative risks, the confidence limits and also the power of the studies, that it is more likely than not that Bendectin is, in fact, associated with limb reduction defects." *Swan Affidavit* at page 7. Dr. Swan would base her opinion on "the methodology that is generally and reasonably relied upon by epidemiologists to analyze, study and interpret data that has been collected, published and unpublished in trying to draw opinions concerning whether or not there is a cause and effect relationship between a drug and a birth defect." *Id.* at page 7-8.

Dr. Jay Glasser is a specialist in biostatistics, epidemiology and biometry. *Hill v. Merrell Dow* transcript, Exhibit 32 at pages 4-7; *Glasser Affidavit* at pages 1-4. Dr. Glasser would testify that "Bendectin is within a reasonable degree of epidemiological certainty associated with congenital disorders, including limb defects." *Glasser Affidavit* at page 7. Dr. Glasser would base his opinion on techniques that are generally and reasonably relied upon by biometrists, epidemiologists and biostatisticians. *Id.*

Dr. Wayne Snodgrass is an associate professor of pediatrics and pharmacology and toxicology. *Rudell v. Merrell Dow* transcript, Exhibit 20 at page 2. Dr. Snodgrass would testify that in his opinion Bendectin is a human teratogen. *Id.* at page 4. Dr. Snodgrass would base his opinion on results of various studies in several disciplines including pharmacology, toxicology, *in vitro* studies, animal studies and human studies. *Id.*

Dr. Johannes Thiersch is a specialist in pathology and pharmacology. *Thiersch Curriculum Vitae*, Exhibit 18. Dr. Thiersch would testify that the chemical composition and physiological activity of a drug are of great interest and importance in determining whether a drug is a teratogen. *Ealy v. Richardson-Merrell* transcript, Exhibit 22 at page 1596.

Dr. John Palmer is a professor of pharmacology. *Palmer Affidavit* at pages 1-4. Dr. Palmer would testify that in his opinion to a reasonable medical and scientific certainty Bendectin is a teratogen. *Id.* at page 7. Dr. Palmer would base his opinion on the pharmacological data, animal studies data, *in vitro* studies data, epidemiological data and other human data. *Id.* at pages 5-7. Dr. Palmer would also testify that he has examined the medical records of the plaintiff children and to a reasonable degree of medical certainty Bendectin was taken at a period of time such as to effect their development and it indeed caused their limb defects. *Id.* at pages 7-8.

The federal courts have held that epidemiological studies are the most reliable evidence of causation in this area. Accordingly, expert opinion which is not based on epidemiological evidence is not admissible to establish causation because it lacks the sufficient foundation necessary under FRE 703. *See, Brock*, 874 F.2d at 311-15; *Richardson*, 857 F.2d at 829-32; *Lynch*, 830 F.2d at 1194. Therefore, expert testimony concluding that Bendectin causes limb reduction defects which is based upon *in vitro* generally studies, chemical structure analyses and animal studies is insufficient to take the issue to the jury. The plaintiffs' experts must be competent to testify that some epidemiological study or recalculation shows a statistically significant relationship between the ingestion of Bendectin and birth defects and that this study forms the basis of their opinion. *Id.* In this case, the plaintiffs have failed to live up to the *Brock* mandate to provide some epidemiological evidence to support their claim that Bendectin is a teratogen. *Brock*, 874 F.2d at 315.

The defendants have introduced evidence that no epidemiological study ever performed has concluded that the use of Bendectin by pregnant women has a statistically significant association to birth defects in those women's children. *Report on the Safety of Bendectin/Diclectin for Use in the Management of Nausea and Vomiting of Pregnancy*, Exhibit J, Defendant's Reply to Affidavits of Plaintiff's Experts Submitted in Opposition to Defendant's Motion for Summary Judgment, at page 2 ("Controlled studies involving over 130,000 patients have not demonstrated any reproducible or consistent association of birth defects with Bendectin exposure. In fact, the results of the epidemiological studies are just what one might expect of an agent without reproductive or teratogenic risks."). *See also Statement of Steven H. Lamm*, Exhibit A, Defendant's Memorandum of Points and Authorities in Support of its Motion for Summary Judgment on the Issue of Causation at page 1 (after reviewing the world's literature on Bendectin and human birth defects, the studies "showed no difference in the risk of birth defects between those infants whose mothers had taken Bendectin during the first trimester of pregnancy and those infants whose mothers had not"). The plaintiffs' experts agree that none of the *published* studies show a statistically significant association between the use of Bendectin and birth defects. *See, e.g., Hill v. Merrell Dow Deposition of Jay H. Glasser*, Exhibit J, Defendant's Memoran-

dum of Points and Authorities in Support of its Motion for Summary Judgment on the Issue of Causation at page 164.

The plaintiffs argue that the absence of statistically significant epidemiological studies does not disprove the fact that Bendectin causes limb reduction defects. *See, e.g.*, Plaintiffs' Opposition to Defendant's Motion for Summary Judgment at 20-27; *Affidavit of Shanna Helen Swan* at pages 4-6. However, this argument directly contradicts the holdings of *Brock, Richardson* and *Lynch*. *See, supra*. The plaintiffs have the burden of proof, and they must come forward with statistically significant epidemiological evidence. The plaintiffs claim that Dr. Gross performed a new epidemiological study on Bendectin, but this is false. He simply recalculated a previously published study and tried to show that there actually was a significant relation between Bendectin and birth defects. *Letter to Thomas H. Bleakley*, Exhibit 40. Dr. Gross' "study" was apparently never published or subjected to peer review, and nowhere does it state that Bendectin sales increased the relative risk of limb reduction defects to a level significantly above 1.0 with a confidence interval that did not include unity. Dr. Gross alleges that this "study" shows "a statistically significant association that is highly significant" (Affidavit at page 11), but his allegation and this evidence is insufficient to take this matter to a jury. *See, Brock*, 874 F.2d at 312-13. Similarly, Dr. Swan's unsupported allegation that the Jick data "statistically significantly associates Bendectin and limb defects" (Affidavit at page 7) is similarly insufficient.

The court feels that the strongest inference to be drawn for plaintiffs based on the epidemiological evidence is that Bendectin could *possibly* have caused plaintiffs' injuries, therefore summary judgment is proper against them. *See, Bieghler v. Kleppe, supra*, 633 F.2d at 533. The court finds that there are no genuine issues of material fact with respect to causation and finds for the defendant on all causes of action.

IT IS SO ORDERED.

Dated: November 1, 1989

15. Court of Appeals' decision affirming the District Court, filed Dec. 20, 1991

UNITED STATES COURT OF APPEALS
For the Ninth Circuit

No. 90-55397

WILLIAM DAUBERT; JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT, a minor; ANITA DE YOUNG, individually, and As Guardian Ad Litem for ERIC SCHULLER,

Plaintiffs-Appellants,

v.

MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation,

Defendants-Appellee.

Appeal from the United States District Court
For the Western District of Texas

(December 20, 1991)

Before: Alex Kozinski and Diarmuid F. O'Scannlain, Circuit Judges, and Stephen M. McNamee,* District Judge.

KOZINSKI, Circuit Judge:

Plaintiffs Jason Daubert and Eric Schuller suffer from limb reduction birth defects. They allege that these defects resulted

* The Honorable Stephen M. McNamee, United States District Judge for the District of Arizona, sitting by designation.

from the fact that their mothers used Bendectin, a prescription anti-nausea drug, during pregnancy. The plaintiffs seek damages from the drug's manufacturer, defendant Merrell Dow Pharmaceuticals.

Plaintiffs' evidence of causation consisted primarily of expert opinion based on *in vitro* and *in vivo* animal tests, chemical structure analyses and the reanalysis of epidemiological studies. Among the contrary evidence proffered by Merrell Dow was the affidavit of a physician and epidemiologist who reviewed all of the available literature on the subject, which included more than 30 published studies involving over 130,000 patients, and concluded that no published epidemiological study had demonstrated a statistically significant association between Bendectin and birth defects. Plaintiffs do not challenge this summary of the published record.

The district court determined that plaintiffs could not meet their burden of proving that Bendectin caused Jason's and Eric's birth defects and granted Merrell Dow's motion for summary judgment. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 727 F. Supp. 570 (S.D. Cal. 1989).

A. Expert opinion based on a scientific technique "is admissible if it is generally accepted as a reliable technique among the scientific community." *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985) (citing *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923)). We impose this requirement because such evidence "creates a substantial danger of undue prejudice or of confusing the issues or of misleading the jury . . . because of its aura of special reliability and trustworthiness." *United States v. Amarel*, 488 F.2d 1148, 1152 (9th Cir. 1973); *see also* Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 HARV.L.REV. 40, 50-52 (1901). Moreover, whether expert opinion can satisfy this requirement is reviewed *de novo* by an appellate court, for "the answer to the question about the reliability of a scientific technique or process does not vary according to the circumstances of each case. It is therefore inappropriate to view this threshold question of reliability as a matter within each trial

judge's individual discretion." *Reed v. State*, 391 A.2d 364, 367 (Md. 1978); *see also United States v. Williams*, 583 F.2d 1194, 1197-1201 (2d Cir. 1978) (applying *de novo* review to the question of the general acceptance of a scientific technique), *cert. denied*, 439 U.S. 1117 (1979).

For expert opinion based on a given scientific methodology to be admissible, the methodology cannot diverge significantly from the procedures accepted by recognized authorities in the field. If it does so diverge, it cannot be shown to be "generally accepted as a reliable technique," *Solomon*, 753 F.2d at 1526, and a district court must exclude it. If such evidence is admitted and materially affects the verdict, a judgment supported by this evidence cannot stand. *See Lindsey v. United States*, 237 F.2d 893, 897-98 (9th Cir. 1956).

B. Whether Bendectin is responsible for limb reduction defects is not a new question in the federal courts. Four of our sister circuits have considered whether plaintiffs could establish such responsibility in the absence of critically analyzed epidemiological studies establishing a connection between the use of the drug and the birth defects. *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989); *Lynch v. Merrell-National Labs.*, 830 F.2d 1190 (1st Cir. 1987) (opinion by Noonan, J., sitting by designation). Three circuits have concluded that the plaintiffs could not establish such a link. Considering largely the same evidence presented to the district court below, these courts held that the animal and chemical studies were insufficient to establish a link between Bendectin and birth defects, *Brock*, 874 F.2d at 313-15; *Richardson*, 857 F.2d at 830; *Lynch*, 830 F.2d at 1194, in part because the plaintiffs' own experts acknowledged the need to verify such data with epidemiological evidence.

Brock, 874 F.2d at 314; *Richardson*, 857 F.2d at 830.[1] These courts were unwilling to allow plaintiffs to rely on reanalyses of epidemiological studies because these reanalyses had neither been published nor subjected to the rigors of peer review. They found the methodology particularly problematic in light of the massive weight of the original published studies supporting the defendant's position, all of which had undergone full scrutiny from the scientific community. *See Brock*, 874 F.2d at 312-13; *Richardson*, 857 F.2d at 831; *Lynch*, 830 F.2d at 1193-96; *see also Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1111 n.8 (5th Cir. 1991) (en banc).[2]

Plaintiffs argue that reanalysis is a generally accepted scientific technique, so it follows that their experts were basing their opinions on a permissible methodology. But the reanalysis of epidemiological studies is generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field. *See* Dore, *A Commentary on the Use of Epidemiological Evidence in Demonstrating Cause-in-Fact*, 7 HARV.ENV'L L.REV. 429, 438-39 (1983) (discussing requirements for original epidemiological studies). Plaintiffs' reanalyses

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[1] *Richardson* and *Lynch* held that expert testimony that Bendectin caused birth defects, based solely on animal and chemical tests and reanalyses of epidemiological studies, was inadmissible under Federal Rule of Evidence 703, and that therefore plaintiffs had failed to present evidence to support a jury verdict in their favor. 857 F.2d at 830-831; 830 F.2d at 1193-96. *Brock* did not hold that the plaintiffs' expert testimony was inadmissible, but did decide that it was insufficient to support the jury's verdict. 874 F.2d at 315.

[2] The Third Circuit has left open the possibility that expert testimony based on the reanalysis of epidemiological studies may be admissible if it can be shown to be reliable and not too likely to overwhelm, confuse or mislead the jury. *See DeLuca*, 911 F.2d at 955 (remanding case for district court to reconsider the admissibility of plaintiffs' expert testimony). Because the Third Circuit has specifically rejected the *Frye/Solomon* "generally accepted" standard, *United States v. Downing*, 753 F.2d 1224, 1236-37 (3d Cir. 1985), we find the court's analysis in *DeLuca* to be contrary to our established precedent and decline to follow it.

do not comply with this standard; they were unpublished, not subjected to the normal peer review process, and generated solely for use in litigation.[3] It does not suffice that the expert's methodology meet *some* of the requirements imposed by the scientific community; it must meet *all* of the essential requirements. Selective borrowing from generally accepted scientific methodology does not satisfy *Solomon*'s rigorous standard.

C. *Lynch*, *Richardson* and *Brock* reflect a well-founded skepticism of the scientific value of the reanalysis methodology employed by plaintiffs' experts; they recognize that "the best test of certainty we have is good science - the science of publication, replication, and verification, the science of consensus and peer review." P. Huber, *Galileo's Revenge: Junk Science in the Courthouse*, 228 (1991). For the convincing reasons articulated by our sister circuits, we agree with the district court that the available animal and chemical studies, together with plaintiffs' expert reanalysis of epidemiological studies, provide insufficient foundation to allow admission of expert testimony to the effect that Bendectin caused plaintiffs' injuries. Accordingly, plaintiffs could not satisfy their burden of proving causation at trial. *See Christophersen*, 939 F.2d at 1109 ("When the contested evidence is essential to the cause of action and the trial court has excluded the evidence, we may decide the appeal . . . solely on the basis of the soundness of the evidentiary ruling. For if we uphold the exclusion of essential evidence, the [review of the summary judgment ruling] becomes academic.").

AFFIRMED.

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[3] Scientific studies conducted in anticipation of litigation must be scrutinized much more carefully than studies conducted in the normal course of scientific inquiry. This added dose of skepticism is warranted, in part, because studies generated especially for use in litigation are less likely to have been exposed to the normal peer review process, which is one of the hallmarks of reliable scientific investigation. *See Brock*, 874 F.2d at 313; *Richardson*, 857 F.2d at 831 n.55; *Perry v. United States*, 755 F.2d 888, 892 (11th Cir. 1985).

16. Denial of panel rehearing and rehearing en banc, filed Apr. 8, 1992

APPENDIX C

UNITED STATES COURT OF APPEALS
For the Ninth Circuit

No. 90-55397, D.C. No. CV-84-2013-G(I)

WILLIAM DAUBERT; JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT, a minor; ANITA DE YOUNG, individually, and As Guardian Ad Litem for ERIC SCHULLER,

Plaintiffs-Appellants,

v.

MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation,

Defendant-Appellee.

(Filed April 8, 1992)

ORDER

Before: KOZINSKI and O'SCANNLAIN, Circuit Judges, and MCNAMEE,* District Judge.

The petition for rehearing is denied. The full court has been advised of the suggestion for rehearing en banc and no active judge has requested a vote. The suggestion for rehearing en banc is therefore rejected. Fed.R.App.P. 35(b).

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* The Honorable Stephen M. McNamee, United States District Judge for the District of Arizona, sitting by designation.

Supreme Court, U.S.
FILED
JAN 19 1993
OFFICE OF THE CLERK

No. 92-102

IN THE
Supreme Court of the United States
OCTOBER TERM, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardian Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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QUESTION PRESENTED

Whether the Federal Rules of Evidence require that expert scientific testimony have an adequate foundation, judged by accepted scientific standards and processes for validating scientific claims.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

No. 92-102

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardian Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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BRIEF FOR RESPONDENT

STATUTES INVOLVED

An appendix to this brief reprints a number of the Federal Rules of Evidence at issue in this case.

STATEMENT

These are two consolidated product liability cases alleging that the drug Bendectin caused petitioners' limb reduction defects. Both courts below concluded that respondent was entitled to summary judgment on the ground that petitioners had failed to come forward with admissible scientific evidence of causation necessary to support a rational jury verdict in their favor. That conclusion was legally proper and should be affirmed.

1. *Background.* "Morning sickness" is experienced by a large proportion of women during the first trimester of pregnancy. The result often is not only acute discomfort but weight loss and lack of nourishment that are unhealthy for both mother and fetus. In some instances, morning sickness leads to severe health problems, necessitating hospitalization. *See* Skolnick, *Key Witness Against Morning Sickness Drug Faces Scientific Fraud Charges*, 263 J. Amer. Med. Ass'n 1468 (1990).

Bendectin is an anti-nausea drug that treats this affliction. The drug was introduced in 1956 and was available until the beginning of 1983, when the costs of litigation and insurance forced its manufacturer to discontinue production. During that period, Bendectin was prescribed by physicians to approximately 30 million women, 17.5 million of whom lived in this country. *See Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 113 S. Ct. 84 (1992).

In the 1970s, individual case reports noted that Bendectin had been taken by the mothers of certain children born with birth defects. Because as many as 2-3% of all babies are born with some birth defects, and Bendectin was so widely taken, chance alone produces an inevitable overlap of Bendectin and birth defects. Against the background of the thalidomide disaster of the 1960s, however, the case reports produced concern about whether Bendectin in fact causes birth defects. Beginning in 1977, law suits were filed against the producer of Bendectin.

The medical scientific community responded to the concerns about Bendectin with intense study. Epidemiologists first approached the question whether Bendectin was causing birth defects by examining data on large numbers of women having babies and looking for any unusually high incidence of any birth defects among women who took Bendectin. These ("cohort") studies detected no causal connection between the incidence of any particular defects, or of defects overall, and the use of Bendectin. In

1980, based primarily on those studies, the Food and Drug Administration conducted a comprehensive review of the safety of Bendectin and concluded that the "'available data do not demonstrate an association between birth defects and Bendectin.'" Green, *Expert Witnesses and Sufficiency of Evidence In Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 Nw. U. L. Rev. 643, 679-80 (1992) (quoting *Department of Health and Human Services News*, No. P80-45 (Oct. 7, 1980)).

Inevitably, when numerous studies are performed to look for an association between two phenomena (*e.g.*, Bendectin use and birth defects), there will be a range of correlations found, even when, over all, the studies show no positive correlation. The essential question in such a situation, answerable only through attempts at replication in other data, is whether the higher numbers reflect nothing more than expected variation among study samples or whether there actually is a positive correlation—here, whether Bendectin and birth defects are in fact related. A powerful tool used by epidemiologists to address this question is a study that examines data on women who gave birth to babies with the specific types of defect in question and asks if a disproportionate number of these women had been exposed to the suspected cause of the birth defect. In the case of Bendectin, these ("case-control") studies did not demonstrate any causal connection between Bendectin and any defect.[1]

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[1] Drs. Cordero and Oakley, of the Centers for Disease Control, summarized the results of all of the Bendectin studies:

> Several case reports of limb reduction defects have raised some concerns about the safety of Bendectin. The hypothesis on the teratogenicity of this drug has been tested in both cohort and case-control studies. . . . When all the studies are considered, it is possible to exclude a risk of birth defects of over 1.2 per 1000. If there is a risk in the use of that drug, it should be less than 0.12%, which is significantly less than the 2-3% risk that any pregnancy has just by chance for serious malformation. This is one example where case reports raised concern

In all, there have been more than 30 published studies involving 130,000 patients relating to the possible teratogenic effect of Bendectin. J.A. 238; *Turpin*, 959 F.2d at 1349 (35 published studies). The remarkable fact about this entire body of research is that no published study has concluded that there is a causal connection, or even a reproducible or consistent association, between Bendectin and any birth defect, and no published study has found any statistically significant association between Bendectin and the sort of birth defects (limb reduction) at issue here. *See* J.A. 212-26, 235, 238. The power of these individual studies is still more dramatic when they are aggregated: "*In toto*, they show no difference in the risk of birth defects between those infants whose mothers had taken Bendectin during the first trimester of pregnancy and those infants whose mothers had not." J.A. 33 (aff. of Dr. Lamm, respondent's expert here but originally court-appointed expert in S.D. Ohio class action); *see also* Einarson, *et al.*, *A Method for Meta-Analysis of Epidemiological Studies*, 22 Drug Intelligence and Clinical Pharmacy 813 (1988) (aggregating 17 Bendectin studies).[2]

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about a specific teratogenic action when epidemiologic studies could show that there was no association.

Cordero and Oakley, *Drug Exposure During Pregnancy: Some Epidemiologic Considerations*, 26 Clinical Obstetrics and Gynecology 418, 424-25 (June 1983) (footnote omitted).

[2] In Canada, where the same medication as Bendectin is still widely used, the government recently "requested an independent review by an expert panel." *Report on the Safety of Bendectin/Diclectin for Use in the Management of Nausea and Vomiting in Pregnancy* (Aug. 11, 1989), *reprinted at* J.A. 212-26. After noting that "[t]here has been no prescription drug that has been more extensively studied for reproductive toxicity[,]" the report concludes that "the prescribing of Bendectin to a human population presents no measurable reproductive risks" and that "[i]t would be a disservice to Canadian women to withdraw this drug from the market." *Id.* at 213, 216.

Faced with this massive body of uniform scientific research, plaintiffs in Bendectin cases responded with four kinds of evidence to try to show causation: (1) studies of animal cells that have been injected with extremely high doses of Bendectin (*in vitro* studies); (2) studies of pregnant animals that have been given extremely high doses of Bendectin (*in vivo* studies); (3) chemical analyses comparing Bendectin to other substances that are alleged teratogens; and (4) "reanalyses" of certain of the published epidemiological studies, claiming (contrary to the published findings) to show that Bendectin use does correlate with limb defects. J.A. 232-35; *see, e.g.*, *Turpin*, 959 F.2d at 1358-60; *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 313-14 (5th Cir. 1989); *Lynch v. Merrell-Nat'l Lab.*, 830 F.2d 1190, 1194-96 (1st Cir. 1987).

With extraordinary consistency, this evidence has been found insufficient to prove causation—by most juries and by most courts (on summary judgment, after verdict, or on appeal). Indeed, of the roughly 2000 Bendectin cases that have been filed—the vast majority of which have already reached final judgment—only one case has resulted in an affirmed jury verdict for the plaintiff. *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C. 1986). Five circuits, including the court below, have ruled as a matter of law that plaintiffs' evidence is insufficient. *Turpin*, *supra* (6th Cir.); *Brock*, *supra* (5th Cir.); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989); *Lynch*, *supra* (1st Cir.).[3] And juries in several separate trials—including, notably, a multi-district case involving 818 consolidated actions—returned defense ver-

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[3] The Third Circuit in *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990), remanded for a more detailed analysis of the foundation for the Bendectin plaintiff's evidence. On remand, the district court found the evidence utterly unfounded and insufficient. *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 791 F. Supp. 1042 (D.N.J. 1992).

dicts that were upheld by the courts. *See, e.g., Wilson v. Merrell Dow Pharmaceuticals, Inc.*, 893 F.2d 1149 (10th Cir. 1990); *Will v. Richardson-Merrell, Inc.*, 647 F. Supp. 544 (S.D. Ga. 1986); *In re Richardson-Merrell, Inc. "Bendectin" Products Liab. Litig.*, 624 F. Supp. 1212 (S.D. Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988); *Cosgrove v. Merrell Dow Pharmaceuticals, Inc.*, 788 P.2d 1293 (Idaho 1990).

Nevertheless, the burden of this avalanche of litigation forced its manufacturer, respondent Merrell Dow, to cease production of Bendectin in 1983, because the cost of insurance rose to almost equal the entire income from sale of the drug. *Brown v. Superior Court*, 751 P.2d 470, 479 (Cal. 1988).[4] With Bendectin now unavailable in the United States (though it remains approved by the FDA), there is no medication of proven effectiveness that physicians may prescribe for the treatment of morning sickness. *See* 1 I. Chalmers *et al., Effective Care of Pregnancy and Childbirth* 501 (1989). As a result, there has been "a two-fold increase in hospitalizations caused by severe nausea and vomiting in pregnancy since the disappearance of Bendectin." Skolnick, *supra*, at 1473.

2. *This Litigation.* The Daubert petitioners filed suit on September 17, 1984, alleging that Bendectin had caused limb reduction birth defects in Jason Daubert, who was born on July 26, 1973. Petitioner DeYoung filed suit on May 11, 1984, alleging that Bendectin had caused limb defects in Eric Schuller, who was born on December 13, 1980. The two cases, initially filed in California Superior Court, were removed to federal court on diversity grounds and consolidated. On August 2, 1989, Merrell moved for summary judgment, arguing that petitioners lacked sufficient evidence to raise a triable issue regarding causation.

[4] Respondent was formerly known as Richardson-Merrell, Inc., the successor to the company (Wm. S. Merrell Co.) that developed and initially marketed Bendectin. For Rule 29.1 statement, see Br. in Opp. i-iv.

a. The district court granted Merrell's motion on November 1, 1989. The court began by noting that "[t]he plaintiff must show that defendant's [product] 'was more probably than not the proximate cause of the accident' to defeat summary judgment and take the issue to a jury." J.A. 228-29 (quoting *Bieghler v. Kleppe*, 663 F.2d 531, 553 (9th Cir. 1980)). Applying that standard—and taking into account the decisions of several other courts in Bendectin cases—the district court scrutinized the proposed testimony of eight expert witnesses relied on by petitioners and concluded that their opinions did not raise a reasonably disputable question for the jury on the issue of causation.[5]

The court reasoned that, given the vast body of epidemiological data concerning Bendectin's effects on human subjects, "expert opinion which is not based on epidemiological evidence is not admissible to establish causation because it lacks the sufficient foundation necessary under [Fed. R. Evid.] 703." J.A. 234-35 (citations omitted). Consequently, the court ruled, three of the four types of evidence relied on by petitioners—animal cell studies, live animal studies, and chemical structure analyses—could not by themselves raise a reasonably disputable jury issue on causation. The court next found that petitioners' fourth type of evidence—a study that "recalculated a previously published study . . . to show that there actually was a significant relation between Bendectin and birth defects" (*id.* at 236) (citation omitted)—was also inadequate to put genuinely in issue the numerous published studies showing no such relation. The court emphasized that petitioners' "'study' was apparently never

[5] Petitioners relied on affidavit and deposition evidence virtually identical to the evidence before the courts in *Brock*, *Lynch*, and *Richardson*. In all three of those cases, the courts of appeals had concluded that the experts' reanalyses of the published epidemiological studies, coupled with their reliance on animal and chemical studies, did not provide a basis for allowing the issue of causation to go to the jury.

published or subjected to peer review" and held that the conclusory assertion by petitioners' experts that their "study" showed a "'statistically significant association [between Bendectin and birth defects]' . . . is insufficient to take this matter to a jury." *Id.* at 236 (internal citation omitted).

b. The Court of Appeals for the Ninth Circuit affirmed. The court began with the proposition that "[e]xpert opinion based on scientific technique 'is admissible if it is generally accepted as a reliable technique among the scientific community.'" J.A. 238 (quoting *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985), and citing *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923)). The court explained that this standard is grounded in the recognition that scientific "evidence creates a substantial danger of undue prejudice or of confusing the issues or of misleading the jury . . . because of its aura of special reliability and trustworthiness." *Ibid.* (internal quotation and citation omitted). It is important, the court added, that "the answer to the question about the reliability of a scientific technique or process . . . not vary according to the circumstances of each case. It is therefore inappropriate to view this threshold question of reliability as a matter within each trial judge's individual discretion." *Id.* at 238-39 (internal quotation and citations omitted).

Applying these principles to the scientific evidence at issue in this case, the court first held that the animal studies and cell-structure analyses put forth by petitioners are "insufficient to establish a link between Bendectin and birth defects." *Id.* at 239. The court pointed out that three other circuits had already reached the same conclusion. J.A. 239-40 (citing *Brock*, 874 F.2d at 313-15; *Richardson*, 857 F.2d at 830; *Lynch*, 830 F.2d at 1194). The court observed that those circuits had reached that conclusion "in part because the plaintiffs' own experts acknowledged the need to verify such data with epidemiological evidence." J.A. 239-40.

The Ninth Circuit then turned to the data relating to humans that petitioners had put forward—that is, their reanalysis—and also found it wanting. The court explained that "the reanalysis of epidemiological studies is generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field." *Id.* at 240. The reanalyses proffered by petitioners, however, "were unpublished, not subjected to the normal peer review process, and generated solely for use in litigation." *Id.* at 241 (footnote omitted). The court thereupon concluded that "[f]or the convincing reasons articulated by our sister circuits, we agree with the district court that the available animal and chemical studies, together with plaintiffs' expert reanalysis of epidemiological studies, provide insufficient foundation to allow admission of expert testimony to the effect that Bendectin caused plaintiffs' injuries." *Ibid.*

INTRODUCTION AND SUMMARY OF ARGUMENT

In opposing summary judgment, petitioners rely exclusively on expert testimony stating that Bendectin causes limb defects in general and their limb defects in particular. They agree that this testimony, to be admissible, must satisfy the requirements of Rule 702, the sole provision in the Federal Rules that authorizes its use. They contend, however, that Rule 702 imposes only two requirements: first, a general determination in the case that this type of "specialized knowledge will assist the trier of fact"; second, a determination that "the witness 'is qualified as an expert' in that specialized field." Pet. Br. 31. That position, which has not been adopted by a single federal court of appeals, is contrary to the language, structure, and policies of the Rules, because it omits a crucial additional requirement of Rule 702—namely, that the specific testimony of each expert have an adequate foundation, judged by the accepted standards of the expert's field.

It is the judge's fundamental duty under the Rules to screen evidence for admissibility to ensure that the body of evidence provides a rationally reliable basis for judgment. This screening requires not only relevancy of evidence, as petitioners recognize, but also, as petitioners almost completely ignore, an adequate foundation for evidence. It is just such a reliable foundation, substituting for the usual requirement of personal knowledge applicable to *non*-expert testimony, that Rule 702 demands for expert testimony. In particular, by restricting expert testimony to "scientific, technical, or other specialized *knowledge* [that] will assist the trier of fact," Rule 702 demands that an expert's testimony be well-grounded in the standards generally followed in his or her field for validating—establishing the truth of—assertions of the type offered. And Rule 703 specifically confirms Rule 702's insistence on community validation standards by allowing hearsay evidence to be part of the foundation for an expert's claims only when the evidence is "of a type reasonably relied upon by experts in the particular field."

As applied to "*scientific* . . . knowledge" in particular, Rule 702 looks to two ways to determine the necessary foundation—(1) the out-of-court scientific process of scrutiny and verification; (2) an in-court assessment of whether the data and reasoning underlying a claim meet scientific standards. This approach reflects the approach followed by the scientific community itself for validating assertions. Certain general principles—*e.g.*, light travels at 186,000 miles per second—are validated through widespread dissemination to other experts in the field, who then test the assertion by analyzing the first scientist's reasoning and attempting to replicate the results. Other, typically non-generic, conclusions—*e.g.*, Jones has an illness—are validated by assuring that the customary scientific methods for making such determinations have been used.

In this case, the testimony proffered by petitioners' experts does not satisfy either of the standards used by the scientific community for validating assertions. Petitioners' experts claim, at a minimum, that Bendectin causes limb defects (in some number of babies who otherwise would not have such defects). In the field of science, that kind of general claim about a substance's "inherent" properties is ordinarily validated through widespread dissemination to, and scrutiny by, the community. That foundational requirement was not met here. In any event, even if an in-court assessment of scientific method could suffice to establish an adequate foundation for testimony about Bendectin's inherent qualities, petitioners have not satisfied that requirement. Their primary reliance on animal studies and chemical analyses in the face of a near-library of available human (epidemiological) data does not comport with community standards. And to the extent that petitioners' experts did consider human data, their patently biased data-selection process, coupled with their inability to explain why they ignored the overwhelming body of data that contradict their conclusion, likewise runs afoul of rudimentary scientific standards.

As we will also show, essentially the same reasoning as applies under Rule 702 would, in this case, render the evidence at issue inadmissible under Rule 703 and under Rule 403. In addition, the unreliability of the foundation means that summary judgment in this case is properly affirmed on the ground that, even if admissible, the evidence is simply too weak to sustain petitioners' challenge to the volume of published causation evidence supporting Merrell Dow.

ARGUMENT

THE TESTIMONY OF PETITIONERS' EXPERTS NECESSARY TO WITHSTAND A MOTION FOR SUMMARY JUDGMENT WAS PROPERLY EXCLUDED BECAUSE IT LACKS AN ADEQUATE FOUNDATION AS REQUIRED BY RULE 702 OF THE FEDERAL RULES OF EVIDENCE.

Petitioners begin their challenge to the Ninth Circuit's decision by arguing that it improperly rests on "a judge-made rule of evidence independent of the Federal Rules." Pet. Br. 14. But the Ninth Circuit decided the case, and we defend the holding, on the basis of the Federal Rules. We agree with the Ninth Circuit that Rule 702, which authorizes the admission of expert testimony in the first place, requires such testimony to have an adequate foundation as judged by community standards, a conclusion strongly reinforced by Rule 703.[6]

A. Rule 702 Bars The Admission Of Expert Testimony That Lacks A Foundation Based On The Accepted Standards Of Validation In The Expert's Field.

Rule 702 allows an expert to testify only to inferences and conclusions that are validated under, or derived from, the accepted standards and methods of that field. This construction rests on a straightforward reading of Rule 702's language and is supported by the language of Rule 703, which governs the "bases of opinion testimony by

[6] The arguments of both petitioners (C.A. Reply Br. 9) and respondent (C.A. Br. 17-18) focused on Rule 702 in the court of appeals, and the Ninth Circuit's opinion relies (J.A. 238) on the legal standard set out in its earlier decision in *United States v. Solomon*, 753 F.2d 1522 (9th Cir. 1985), which expressly relied on Rule 702 of the Federal Rules (*id.* at 1525). The Ninth Circuit also pointed out (J.A. 240) that several other courts, following the same foundational approach to expert testimony, had relied on Rule 703, rather than Rule 702. *See, e.g., Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 830-31 (D.C. Cir. 1989); *see also* cases cited at note 24, *infra*.

experts." It also comports with the structure of the Rules as a whole, which assign to the court (and not the trier of fact) the responsibility for ensuring that *all* evidence rests on a reliable foundation. It is further buttressed by the fact that, when the Federal Rules of Evidence were enacted in 1975, the federal courts routinely made this kind of foundational inquiry with respect to expert scientific testimony, and there is no reason to suppose, as petitioners do, that Congress intended to eliminate this well-established evidentiary practice without ever saying so.[7]

1. *The Language of the Rules, Reinforced by the Advisory Committee Notes, Demonstrates that an Expert's Testimony Must Be Validated, to the Extent Possible, According to Accepted Standards in the Field.*

Rule 702 states:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

The critical term "knowledge" demands more than individual belief or speculation, but instead refers to inferences or assertions that are grounded in the standards reliably used to support such claims. Other language of Rule 702, as well as Rule 703, confirms this interpretation.

a. *Scientific Knowledge.* Rule 702 requires that what an expert is testifying to itself be "scientific, technical,

[7] Although this case involves only scientific testimony, the analysis in the text applies as well to "technical or other specialized knowledge" under Rule 702. Indeed, unless a field has a set of rational and well-recognized standards of validation, testimony in that field cannot be admitted because it is not "knowledge" but superstition or belief. That is why astrologers and phrenologists are not permitted to testify in federal court.

or other specialized knowledge." Thus, the Rule says that when "scientific . . . knowledge will assist the trier of fact . . . , a [qualified] witness . . . may testify *thereto*." (Emphasis added.) The critical connecting term "thereto" unambiguously requires that the substance of the expert's testimony be "scientific knowledge." The testimony may, of course, be "in the form of an opinion or otherwise." But as the Advisory Committee Note indicates, the Rule uses "opinion" *not* to refer to general "principles" themselves, but only to the application of such principles, through inferences, to the particular case. Rule 702, Adv. Comm. Note ("dissertation or exposition of scientific or other principles" is not "opinion," which is "suggesting the inference which should be drawn from applying the specialized knowledge to the facts"). And even when offering an "opinion," a scientific expert must be testifying "[]to" "scientific knowledge."

These words naturally mean that an expert must be testifying to more than merely his or her own view on a scientific issue. Rule 702 does not allow an expert to offer "beliefs" or "hypotheses" or "theories" or "claims" or "assertions" or "evidence" or "testimony"; instead, it limits expert testimony to "knowledge." Even by itself, "knowledge" ordinarily requires, at a minimum, appropriate validation for the proposition—*i.e.*, "good grounds" for the belief based on what is known. *See Webster's Third New International Dictionary* 1252 (1986). And when used as part of the phrase "scientific, technical, or other specialized knowledge," the term naturally refers to grounds that are deemed good by the relevant scientific, technical, or other specialized field—that is, to claims that are validated, or derived, according to the accepted standards in the relevant field. *See* J. Kourany, *Scientific Knowledge: Basic Issues in the Philosophy of Science* 112 (1987) (hypotheses "must prove their mettle" to become "part of scientific knowledge"). Rule 702's language, naturally read, thus requires validation to the extent possible—*i.e.*, a foundation, or good reason for acceptance

as valid—based on established standards in the expert's field.[8]

Rule 702's use of the word "knowledge" to require validation by appropriate standards, or more than mere personal views, is consistent with the usage of that term in other Rules and the Advisory Committee Notes. First, it is supported by Rule 602. In referring to "personal *knowledge*," Rule 602 requires appropriate validation for the testimony in personal observation, which, of course, is generally thought to be the most reliable way for establishing the truth of non-expert factual assertions. *See* Rule 602, Adv. Comm. Note (witness "'must have had an opportunity to observe, and must have actually observed the fact'" to establish the "foundation" requirement of "personal knowledge"). Moreover, the "*personal* knowledge" of Rule 602 contrasts directly with the more-than-merely-personal "scientific, technical, or other specialized knowledge" of Rule 702.

Similarly, the Advisory Committee Note to Rule 702, in referring to a "dissertation or exposition of scientific or other principles," plainly treats the "knowledge" referred to by the Rule as more than mere personal opinion. So, too, when the Advisory Committee Note observes that "there are other techniques for supplying" the "scientific, technical, or other specialized knowledge," it necessarily treats this knowledge as something other than any particular witness's own beliefs (since it can be supplied

[8] It is, of course, perfectly conceivable for each of several competing scientific (or other expert) claims to be validated to the extent possible at any given time. The very reason that scientists can disagree, and that scientific knowledge advances as it does, is that what is known at a particular moment does not uniquely predetermine all answers to new questions. Accepted standards and available evidence thus may not rule out either of two competing, but well-reasoned, conclusions. By the same token, however, they do rule out some answers. What validation means, therefore—all it *can* mean, given the ever-evolving body of knowledge—is good reason for acceptance as true, based on what is known at the time.

without a witness at all). And, notably, the two obvious alternative methods of supplying such knowledge—judicial notice under Rule 201, where there is no need for elaboration or explanation on the witness stand; and learned treatises under Rule 803(18)—both require validation by accepted standards. Thus, Rule 201 uses the term "known" to mean what is "not subject to reasonable dispute"; and Rule 803(18) requires that the treatise ("written primarily and impartially for professionals, subject to scrutiny and exposure for inaccuracy") be "established as a reliable authority." *See* Rule 803(18) & Adv. Comm. Note.

Finally, the logic of Rule 702's requirement that the expert be "qualified . . . by knowledge, skill, experience, training, or education" supports the view that the testimony itself must have a sound foundation of validity in accepted standards. As one scholar has aptly noted, "Rule 702's requirement that the expert who testifies be qualified to do so would be incongruous, to say the least, and ludicrous, to speak the worst, if the scientific underpinning for the expert's opinion were not also qualified." Starrs, *Frye v. United States Restructured and Revitalized: A Proposal to Amend Federal Evidence Rule 702*, Jurimetrics J. 249, 251 (Spring 1986). Hence, the requirement of expertise itself insists that the testimony be more than mere personal belief, even by an individual with impressive credentials: its validity must be well-grounded according to independent community standards.[9]

[9] Significantly, in the Ninth Circuit, petitioners themselves, far from contesting the reading of Rule 702 as embodying the notion of "acceptance" in the relevant field, treated Rule 702 as reflecting just such a notion. Appellants' C.A. Reply Br. 9, 10 ("Courts apply Rule 702 to determine whether the principle, procedure or technique is generally accepted in the scientific community."; referring to "[t]he 'general acceptance' standard of Rule 702"). Petitioners argued only that Rule 702 does not apply to "the substance of the opinions" but only to "the *techniques* that are being analyzed." *Id.* at 10. This distinction, however, concedes that accepted standards

b. *Will Assist the Trier of Fact.* The natural "accepted-standards-for-validation" meaning of "scientific . . . knowledge" is reinforced by Rule 702's requirement that expert testimony must "assist the trier of fact to understand the evidence or to determine a fact in issue." As an initial matter, the Rule is properly construed to require that each particular expert's testimony must "assist the trier of fact." It is unreasonable to read Rule 702 as petitioners do—that is, as indicating that if knowledge on a scientific issue would help the jury, then any expert may offer any view that is on the same topic, even if that particular testimony will *not* assist the trier of fact. *See* Pet. Br. 31-34. Any such reading is undermined by the Rule's careful tying of the expert's testimony (through the term "thereto") to the "scientific, technical, or other specialized knowledge [that] will assist the trier of fact." It is also contrary to the Advisory Committee's statement that "[w]hen opinions are excluded, it is because they are unhelpful." More pointedly, it is just not plausible to attribute to Congress an intent to allow the introduction of unhelpful expert testimony—which, by definition, petitioners' parsing of Rule 702 allows—on some sort of "in for a penny, in for a pound" theory.

The "will assist" standard, as applied to scientific assertions, necessarily "assumes that the evidence is based upon scientifically recognized and defensible methods." Amer. Soc. Law, Medicine & Ethics *Amicus* Br. 3. Scientific evidence, like other evidence, will not assist the jury in its *proper* task—understanding the evidence, then reaching a judgment that is based on evidence that actually has a reliable foundation, not just on evidence that the jury might believe is true—unless it has "scientific merit." Law Professors' *Amicus* Br. 8; *see id.* at 13, 15. Thus, the validity of an expert's assertion must itself have a reliable foundation—in the accepted standards

determine what can be testified to under Rule 702. In any event, it is hard to see how to derive petitioners' distinction from Rule 702.

appropriate to the validation of that type of assertion—in order for the claim to assist the trier of fact."[10]

c. *Rule 703.* Rule 703 confirms the essential prerequisite for admission of expert testimony—a foundation, or good grounds for acceptance as valid, based on the standards followed in the relevant field of expertise. Rule 703 governs the "bases of opinion testimony by experts." It provides that an expert may base an "opinion or inference" on any "facts or data" that are "perceived by or made known to the expert at or before the hearing": the bases thus may be (1) perceived at the hearing (the expert looks at the gun in evidence while on the stand); (2) perceived before the hearing (the expert tested the gun before trial); (3) made known at the hearing (the hypothetical question); (4) made known before the hearing (hearsay). *See* Rule 703, Adv. Comm. Note. Expert opinions based on data in the last category were inadmissible at common law and would, of course, be inadmissible under Rule 602's requirement of "personal knowledge" as a foundation for testimony. *See* Rule 703, Adv. Comm. Note; *see also* Rule 802. But Rule 703

[10] The same conclusion can and should be reached under Rules 401 through 403 (some of whose language the Ninth Circuit used in its opinion, J.A. 238). Thus, Rule 401, defining "relevance," directs the court to inquire into the "principles evolved by experience or science" to determine relevance (Rule 401, Adv. Comm. Note). Rule 403 then allows exclusion of evidence whose probative value is substantially outweighed by "unfair prejudice," *i.e.*, any kind of "undue tendency to suggest decision on an improper basis" (Rule 403 & Adv. Comm. Note). A foundation in valid principles is necessary for evidence to have probative value in the broadest sense, and the absence of a reliable foundation renders evidence an improper basis for decision. What Rule 702 makes explicit for expert testimony, therefore, can also be derived from the more general provisions of Rules 401-403. *See* Br. *Amicus Curiae* of Chamber of Commerce. Of course, the close relationship of these requirements is hardly surprising given the integrated nature of the Rules as a Code (*see* Rule 102); and that relationship explains the reference to the relevance rules in some of the cases dealing with scientific evidence.

makes an express exception to Rule 602 (which states that "[t]his rule [602] is subject to the provisions of rule 703, relating to opinion testimony by expert witnesses"), so as "to bring the judicial practice into line with the practice of the experts themselves when not in court." Rule 703, Adv. Comm. Note (observing that, *e.g.*, physicians base diagnoses on what would be hearsay statements in court, including statements of patients, relatives, nurses, and other physicians).

In deciding to broaden the permissible bases for expert opinions, however, Congress explicitly revealed the basic foundational principle that, as reflected in Rule 702, governs *all* expert testimony. Opinions based on otherwise inadmissible hearsay are to be admitted only if the facts or data are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Rule 703. The rule itself, in short, requires that the foundation for the opinion's validity conform to the accepted standards in the field, a requirement that brings Rule 703 "into line" (Adv. Comm. Note) not only with accepted scientific practice but with the foundational requirement of Rule 702. Rule 703, therefore, even as it eliminates a pre-existing evidentiary impediment to the admission of properly validated expert opinions, makes clear that those opinions must be properly validated under community standards.

2. *The Rules of Evidence as a Whole Confirm this Interpretation of Rule 702.*

Petitioners' "expert-qualification only" view of Rule 702 also reflects a fundamental misunderstanding of the place of Rule 702 in the Rules of Evidence as a whole. Seen in that context, Rule 702 can only be reasonably construed to serve the essential function of ensuring a reliable foundation appropriate to expert testimony, one that substitutes for the usual (but inapplicable) requirement of personal knowledge. Indeed, a judicially applied

foundation requirement is particularly important for expert testimony. By contrast, petitioners' view leads to the highly anomalous result that, among all witnesses, experts alone need not have a reliable foundation for their testimony.

a. Whereas petitioners concentrate virtually all of their "statutory context" discussion on the "relevancy" standards of article IV of the Rules (*see* Pet. Br. 19-28), they all but ignore (*but see id.* at 32 n.61, 36) the second overarching requirement for admissibility of evidence: a proper "foundation," or basis for validity, without which even relevant evidence cannot be admitted. Rule 602, Adv. Comm. Note. This requirement is every bit as important as the requirement of relevancy, for it gives effect to "the common law insistence upon the most reliable sources of information." Rule 602, Adv. Comm. Note (internal quotation marks omitted). And it is every bit as pervasive: Rule 602 declares in sweeping terms that testimony must be based on "personal knowledge." Article VII's provisions regarding expert testimony, as well as Article VIII's provisions regarding hearsay testimony, are then extensively concerned with carefully crafting exceptions to that pervasive requirement. *See* Law Professors *Amicus* Br. 21 ("Articles VI, VII, and VIII designate whole areas in which otherwise relevant evidence is excluded.").[11]

It is within the setting of this fundamental and pervasive insistence on a reliable foundation that Rule 702 must be understood.[12] After all, article VII's rules on

[11] Likewise, articles IX and X impose certain restrictions on the admission of writings and similar evidence—again insisting on a foundation in reliability (through authentication and identification, Rules 901-903, and the general requirement of an "original," Rule 1002), over and above the mere requirement of relevancy.

[12] Rule 701 addresses lay opinion testimony. It insists that any lay opinion be "rationally based on the perception of the witness." It would seem that by a parity of reasoning an expert's opinion must also be "rationally based" on the material that is its foundation.

expert testimony are placed in the Rules after, and as an explicit exception to, Rule 602's (and 701's) broad restriction of testimony to what is based on personal knowledge—a standard that scientific generalizations of the sort at issue here can rarely if ever meet. *See* Rule 602 (referring to Rule 703). It makes little sense to attribute to Congress, in the context of this broad and traditional insistence on an adequate foundation to assure reliability of testimony, a decision to abandon any such requirement when it comes to expert testimony, demanding instead only that the expert be qualified. It is far more plausible to read article VII as requiring, for all expert assertions, a reliable foundation that substitutes for the usual guarantee of personal knowledge.[13]

b. The judge's function in applying this foundation requirement for the admission of expert testimony is an entirely familiar and expressly authorized one, thus refuting any suggestion that construing Rule 702 to embody a foundation requirement somehow interferes with the function of the trier of fact. The Rules explicitly assign to the judge the critical function of shaping, and limiting, the body of evidence that will ultimately be presented to the trier of fact for fact finding. Rule 104(a) instructs the judge to make all determinations not only of the qualifications of a witness but, in addition, of the "admissibility of evidence"—determinations that often include factual inquiries. *See* Rule 104(a), Adv. Comm. Note. And Rule 104(b)—recognizing that no evidence stands in isolation but becomes a proper basis for a

[13] Indeed, the hearsay exceptions in article VIII were explicitly crafted with an eye toward just such substitute guarantees. *See* Art. VIII, Adv. Comm. Note (following common-law approach to recognize exceptions only "under circumstances supposed to furnish guarantees of trustworthiness"); Rule 803(24) ("circumstantial guarantees of trustworthiness"); 804(b)(5) (same). Article VII is naturally construed likewise to require a reliable foundation.

rational decision only through connection to valid principles and the other evidence in the case—instructs the judge to keep track of, and insist upon, the need for each piece of evidence to be connected up to other evidence so as to ensure that "the foundation evidence is sufficient." Rule 104(b), Adv. Comm. Note.[14]

In short, the Rules explicitly impose on judges the duty to screen evidence based on its substance. It would be an extraordinary abdication of this judicial function to treat expert testimony as the one kind of testimony not screened for a reliable foundation by judges. It is hardly surprising, therefore, that every federal circuit agrees that the Rules contemplate precisely such a foundational inquiry for expert testimony.[15]

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[14] *Barefoot v. Estelle*, 463 U.S. 880 (1983), which is relied on by petitioners (Pet. Br. 39), hardly contradicts these clear provisions of the Rules. For one thing, it is a constitutional case, not decided under the Federal Rules of Evidence. Moreover, *Barefoot* involved a dispute, not over the admissibility of the substance of the testimony, but only over whether the testimony could be offered by an expert in his expert capacity. The Court emphasized that it had previously decided that the particular fact determination (a prediction of dangerousness) was one that lay jurors could make and so found no reason as a matter of due process to forbid expert testimony on that same issue. In any event, the Court in *Barefoot* did not undertake a full analysis of the Federal Rules or purport to hold, what Rule 104 makes impossible, that there is no ordinary screening function for federal judges, by which they ensure not only relevancy but a foundation as well. Later decisions, of course, have confirmed this function. *See Huddleston v. United States*, 485 U.S. 681 (1988); *Bourjaily v. United States*, 483 U.S. 171 (1987).

[15] The disagreement among the circuits concerns the nature of the testimony-specific foundation requirement, not the existence of such a requirement; and no circuit has treated the relevant standards in the expert's field as irrelevant to the foundational inquiry. Thus, for example, the Third Circuit in *DeLuca v. Merrell Dow Pharmaceuticals*, 911 F.2d 941 (1990), and *United States v. Downing*, 753 F.2d 1224 (1985), though rejecting (on policy grounds) both the "general acceptance" standard and a rule excluding testimony based on unreviewed, unpublished materials, endorsed no rule even remotely resembling that advanced by petitioners here. Rather,

c. A reliable foundation for testimony is of greater, not lesser, importance when *expert* testimony is at issue. It has long been recognized, as Learned Hand observed in 1901, that expert testimony has a heightened potential to sway a jury "because of its aura of special reliability and trustworthiness." *United States v. Amarel*, 488 F.2d 1148, 1152 (9th Cir. 1973). *See* Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 Harv. L. Rev. 40, 50-52 (1901). At the same time, juries often have a diminished capacity to assess expert testimony on its merits. *See* Tribe, *Trial by Mathematics: Precision and Ritual in the Legal Process*, 71 Harv. L. Rev. 1329, 1331 (1971).

Lay factfinders' difficulty with assessing expert testimony on its merits has at least two aspects. First, the jury may simply not be able to understand the testimony —at least not well enough to resolve disputes between experts on complex matters of statistical and other scientific inference. Second, evaluating an expert claim on its merits is not just a matter of understanding it well enough to assess the "internal" soundness of the expert's reasoning. At least for scientific experts, there is an additional step. Because science is empirical, evaluation is a matter of testing the claim against reality—seeing how it fits with all of the available evidence and attempting to replicate the evidence underlying it. But the finder of fact in a judicial proceeding simply cannot do what scientists would often do to resolve disputes of the sort that a "battle of the experts" can produce: carefully review the available literature and, if that proved inconclusive, conduct new

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the factors enumerated in *Downing, including* general acceptance, demand that the trial judge screen expert testimony to determine "the soundness and reliability of the process or technique used in generating the evidence." 753 F.2d at 1237. And when the district court followed that approach on remand in *DeLuca*, a Bendectin case involving substantially the same oft-recycled packet of evidence as was proffered here, it held that the testimony lacked an adequate foundation. *See DeLuca*, 791 F. Supp. at 1057-59; Comment, *DeLuca v. Merrell Dow Pharmaceuticals, Inc.: Statistical Significance and the Novel Scientific Technique*, 58 Brooklyn L. Rev. 219 (1992).

experiments or studies. Indeed, if even the process of peer review for publication lacks the resources to undertake this complete process (Chubin *Amicus* Br. 11), it is fanciful to imagine that a jury, faced with two opposite presentations of evidence (each shaped by litigation strategy), could set about to survey the relevant literature, conduct new experiments or studies, and come to its own view of the validity of the asserted scientific generalization.[16] A foundation filter, therefore, is particularly important for expert testimony.[17]

3. *The Pre-1975 Background of the Rules Supports this Interpretation.*

The final reason for concluding that Rule 702 imposes a validation-based foundational requirement is that such a requirement has long and uniformly been recognized at common law. It would thus be surprising, to say the least, to think that Congress had intended to eliminate this requirement without ever saying so anywhere in the legislative proceedings leading to the enactment of the

[16] Of course, juries customarily rely on demeanor in judging a witness's veracity in reporting personal observations. But except for cases of falsification of data, veracity is rarely the issue when judging the validity of a scientific proposition. *See* P. Medawar, *Advice to a Young Scientist* 39 (1979) ("*[T]he intensity of a conviction that a hypothesis is true has no bearing on whether it is true or false.*") (emphasis in original).

[17] Petitioners acknowledge that "[o]n the issue of causation in a toxic tort case, common sense dictates that the jury is incapable of making a decision without the benefit of expert testimony." Pet. Br. 33. But if the jury cannot decide the causation issue without expert assistance, and it is incapable of independently resolving a technical battle of the experts, it cannot rationally decide the causation issue. Of course, as we have noted, neither the interpretation we offer here nor even more stringent ones can eliminate all "battles of the experts." *See* note 8, *supra*. But that recognition, based on the limitations of scientific knowledge, hardly supports the let-it-all-in approach urged by petitioners. It is far more sensible to suppose that Congress wanted to limit this sometimes-inevitable battle to disputes over well-founded contested theories or situations where the application of such theories reasonably can lead to different conclusions.

Federal Rules. On the contrary, the natural and well-accepted inference in these circumstances is that Congress intended to perpetuate the prior practice. *See United States v. Abel*, 469 U.S. 45, 51-52 (1984) (given "state of unanimity" regarding evidentiary practice before the Federal Rules, it is "unlikely that [Congress] intended to scuttle [it]" without providing a clear indication of such intent). *See also* Pet. Br. 23 n.49 ("the common-law background can be pertinent to interpreting *ambiguities* in the Rules").

There is no dispute in this case that, prior to 1975, the federal courts required that expert scientific testimony had to rest on a foundation that met the standard of "general acceptability" in the scientific community. While that principle is often referred to as the "*Frye* rule" (*Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923)), the policy underlying the approach had been recognized earlier. *See* Hand, *supra*. By 1975, the requirement was pervasive. *See United States v. Alexander*, 526 F.2d 161, 163 n.3 (8th Cir. 1975) (the "federal courts of appeals continue to subscribe to [the] 'general scientific acceptability' criterion") (citations omitted); *United States v. Skeens*, 494 F.2d 1050, 1053 (D.C. Cir. 1974); Giannelli, *The Admissibility of Novel Scientific Evidence:* Frye *v.* United States, *a Half-Century Later*, 80 Colum. L. Rev. 1197, 1228-29 (1980). Most state courts likewise followed such a standard. *Ibid.*; P. Giannelli & E. Imwinkelreid, *Scientific Evidence* § 1-5, at 10-11 (1986).

As petitioners implicitly concede, however, there is not a word in the Advisory Committee Notes or in any hearing, report, or floor debate in Congress that states an intent to abandon that approach. *See* Giannelli, *supra*, at 1229; P. Giannelli & E. Imwinkelreid, *supra*, at 29. In these circumstances, as the Court in *Abel* held specifically with respect to the Federal Rules, the customary inference is that Congress was working no radical unannounced change in the governing standard. *See* S.

Saltzburg & M. Martin, *Federal Rules of Evidence Manual* 15 (5th ed. 1990); Giannelli, *supra*, at 1228-29. *See generally Pennsylvania Dep't of Pub. Welfare v. Davenport*, 495 U.S. 552, 563 (1990); *United Sav. Ass'n v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 380 (1988); *Emil v. Hanley*, 318 U.S. 515, 521 (1943).

To be sure, this inference of presumed continuity may be defeated if the statutory text disproves it. *See Bourjaily v. United States*, 483 U.S. 171 (1987). In this case, however, there is no basis for rejecting the inference. Rather, the text of Rule 702, through its requirement that the expert testify to "scientific . . . knowledge [that] will assist the trier of fact," reinforced by Rule 703, with its "reasonably relied upon by experts" standard, affirmatively embodies a foundational requirement that carries forward the basic idea governing pre-1975 federal court practice: that a claim be tested for an adequate foundation under accepted standards for validation. *See* Law Professors' *Amicus* Br. 5 n.3 ("the generally prevailing view appears to situate [*Frye*] in Rule 702"); Imwinkelreid, *The "Bases" of Expert Testimony: The Syllogistic Structure of Scientific Testimony*, 67 N.C. L. Rev. 1, 1-2 (1988); P. Giannelli & E. Imwinkelreid, *supra*, § 1-5, at 29-30.

* * *

In summary, a straightforward application of traditional principles of statutory construction demonstrates that Rule 702 of the Federal Rules of Evidence requires a judicial determination not only (1) that resolution of a question warrants the use of expert testimony and (2) that a particular expert is qualified in his or her field, but also (3) that the testimony proffered by an expert rests on a foundation reflecting the generally accepted standards in that field for validating expert assertions. Petitioners have come forward with no basis for supposing that this

long-standing, common-sense requirement was omitted by Congress.[18]

B. For Some Scientific Claims, The Necessary Foundation Requires Out-Of-Court Passage Through The Process Of Scientific Community Scrutiny And Verification; For Other Claims, The Foundation Requires Conformity Of The Underlying Reasoning To Accepted Scientific Standards For Validation Of That Type Of Claim.

Application of the "accepted standards" foundational requirement of Rule 702 directly leads to two doctrinal rules for scientific testimony. In the scientific community, the accepted standards for validation of a claim depend largely on the nature of the claim. Some claims—typically those stating a general scientific proposition—simply cannot have a reliable foundation if they have never passed

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[18] Petitioners' challenge to the foundational rule as improperly judge-made (Pet. Br. 16-28) is beside the point because, as just shown, the requirement is squarely located in Rule 702. For that reason, this case presents no opportunity to consider the scope of interstitial lawmaking authority conferred on the federal courts under the Federal Rules of Evidence. *See* Rule 102 ("[t]hese rules shall be construed to secure . . . promotion of *growth and development of the law of evidence* to the end that the truth may be ascertained and proceedings justly determined") (emphasis added).

Similarly, petitioners' argument based on *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), also rests on the conclusion that the courts below applied a "judge-made rule." Pet. Br. 41. While their *Erie* analysis is probably flawed even on that assumption (*see Byrd v. Blue Ridge Rural Elec. Coop., Inc.*, 356 U.S. 525 (1958)), the argument is obviously frivolous in view of the fact that the evidentiary requirement we rely on is part of the Federal Rules, which were enacted by Congress. Even petitioners do not suggest that *Erie* bars Congress from enacting a statute governing the reliability of judgments in the federal courts. (We also note that, because many States adopt testimony-specific reliability screens at least as demanding as we suggest, petitioners' proposal itself would apparently cause outcome-determinative divergence from state evidentiary practice as much as, if not more than, our interpretation: evidence excluded in state court would, in petitioners' view, be admitted in federal courts in the same case.)

the test of out-of-court scientific community scrutiny. Other claims—typically those applying accepted scientific propositions to particular historical occurrences—must be assessed in court for conformity of their reasoning to accepted standards of validation.

1. *Some Scientific Claims Cannot Have an Adequate Foundation Without Community Scrutiny and Verification.*

It is an essential precondition to the validation of certain types of scientific claims that they be "accessible to the skepticism of the larger scientific community." Carnegie Comm'n *Amicus* Br. 27. It is "under the glare of pluralistic criticism" (*id.* at 5) that the necessary process of independently scrutinizing a scientist's reasoning process, attempting to replicate the results, and questioning for consistency with other relevant evidence goes forward.[19] Indeed, for that reason, scientific practices that inhibit independent scrutiny of results are recognized as even *ethically* questionable. *See Responsible Science* 5-6, 25, 28, 140; *see also* note 19, *supra*. Thus, it is central to the meaning of "scientific knowledge," as applied to certain types of scientific claims, that it "is the product of a *collective* human enterprise to which scientists make individual contributions which are purified and extended by mutual criticism and intellectual cooperation" and "has been through a thorough process of criticism by well-motivated and skillful experts who have not been able to detect any significant errors." J. Ziman, *Reliable Knowledge* 2-3, 108 (1978).

[19] *See* 1 Panel on Scientific Responsibility and the Conduct of Research, Committee on Science, Engineering, and Public Policy, National Academy of Sciences, *Responsible Science: Ensuring the Integrity of the Research Process* 20 (1992) ("scientific judgment, experimentation, and error-correction . . . are intrinsic to the development of new scientific knowledge"); *id.* at 25 ("Science is not only a body of information, composed of current knowledge, theories, and observations, but also the process by which this body of knowledge is developed. Furthermore, the scientific process is a social enterprise that involves individuals and institutions engaged in developing, certifying, and communicating research results."); Rothman *Amicus* Br. 8 (" 'replication' . . . is fundamental to science. . . . 'Replicating' is the process by which one scientist tries to verify the procedures and analyses undertaken by other scientists.").

This requirement—a requirement of the scientific community itself—normally applies to general propositions that, not being statements of historical fact, must be equally true in every scientist's laboratory and that can only be established by repeated testing against the evidence of observation and experiment. Of course, the most basic requirement of this understanding of "scientific knowledge" is that a scientific hypothesis be written up, with supporting reasons, and disseminated to the scientific community for the process of independent scrutiny and verification to get under way. And this requires that a proposition be found in the "literature" to which that community normally turns, which assuredly does not include courtroom transcripts.

Where scientific generalizations are asserted, an individual scientist cannot claim "scientific knowledge" based simply on that individual's unreviewed analysis—especially if the "analysis" is unwritten or fails explicitly and in detail to set out its data, premises, and methodology. There are too many opportunities for error, particularly on matters where no individual scientist may even know of all the research being done simultaneously elsewhere in the world and where reasoning, such as statistical inference, is difficult and fraught with potential for mistake. It is the writing up of a chain of reasoning and evidence, followed by independent scrutiny and acceptance, that normally defines a scientific generalization as "scientific knowledge."[20] An assertion that has not been sub-

[20] *See* Black, *A Unified Theory of Scientific Evidence*, 56 Ford. L. Rev. 595, 601 (1988) (science "relies on the give and take of criticism, testing, experimentation, and review to determine what is valid"); D. Hull, *Science as a Process* 361-62 (1988) ("Science

mitted to this community process cannot lay claim to that status. *Cf.* Rule 803(18), Adv. Comm. Note (learned treatises reliable because "written primarily and impartially for professionals [and] subject to scrutiny and exposure for inaccuracy").[21]

Several of petitioners' *amici* appear to dispute this contention, claiming that the decision below will unduly rigidify scientific thinking by insisting on universal (or near universal) agreement before a proposition can be testified to in court. These concerns are fanciful: our approach to testimony about generic scientific principles that can reasonably be subjected to general community scrutiny does not require "unanimity" or exclude testimony based on one side of a genuine debate in the scientific community. Instead, it requires (where appropriate) that a scientist write up his or her analysis and disseminate it through normal channels calculated to reach those independent scientists interested in the problem and capable of evaluating the hypothesis; it then allows the scientist

is a social process in which scientists evaluate and criticize each other's work, leading to successive improvement."); *id.* at 367 ("If science is to be cumulative and self-correcting, then it is inherently social."); *id.* at 377 ("If science is a selection process, transmission is necessary.").

[21] Contrary to petitioners' worry (Pet. Br. 47-49; *see also* Chubin *Amicus* Br.), this requirement does not insist rigidly on "peer reviewed publication," even for generalizations that require community scrutiny for acceptable validation. Notably, the Ninth Circuit did not hold otherwise: its legal requirement was submission of a written paper to the scientific community for "verification and scrutiny by others in the field." J.A. 240. In some circumstances, certainly, this process can appropriately take place through other means of dissemination, such as government reports or reports by expert bodies. What is essential—a *necessary*, not a *sufficient* condition—is dissemination of full written reasoning through normal channels of scientific communication. It is because peer reviewed publication is the usual means of communication in the fields relevant to this case, and indeed encompassed the heart of the material petitioners' witnesses either sought to contradict or "reanalyze," that the Ninth Circuit correctly referred to this process.

to establish a foundation for the claim that the hypothesis has passed the scientific process of community scrutiny, if there is in fact reasonable independent agreement that this hypothesis is valid under accepted scientific standards and a reasonable explanation of the basis for disagreeing with dissenting scientists.[22]

Contrary to the suggestion of one of petitioners' *amici*, moreover, the Ninth Circuit's insistence on this rational process of scientific inquiry does not promote a mistaken and destructive image of science, one that treats certain views as simply unworthy of consideration and that conjures up Seventeenth Century images of "establishment" condemnation of "heresy." *See Amicus* Br. of Physicians, Scientists, *et al.* at 7-16. Far from resting on a view of science as enforcing orthodoxy, Rule 702's and Rule 703's incorporation of scientific standards for validating claims necessarily assumes that the scientific process is precisely the opposite of "closed." These rules treat the scientific process as open to new ideas and ready and willing to entertain and, ultimately, to be convinced by them. This may not have been a fair assumption at the time of Galileo, but the very reason for allowing scientific testimony, and for referring to scientists' standards for validation, is that Congress has determined that it is a correct assumption today—even with the inevitable de-

[22] It is worth noting here that the legal system sensibly does not treat evidence in precisely the same way as does the scientific community. At least theoretically, the scientific community stands ready to consider all evidence. But the federal legal system, like every state system as far as we are aware, places limits on the types of evidence that are reliable enough to serve as a basis for a legal judgment: the pervasive requirement of personal knowledge is one such limit; the conceded requirement of witness "qualification" is another. Restricting the bases for a legal judgment—which may place a person in prison or drive a beneficial medicine off the market—in no way conflicts with the commitment of *science* to consider all evidence.

mand of the scientific community that revolutionary theories have a burden to meet in proving themselves.[23]

More important, perhaps, it is petitioners' view, rather than ours, that would have a stifling effect on the scientific process. Their view inevitably places a premium on experts' *withholding* their analyses from the ordinary channels of communication among scientists: under petitioners' approach, such analyses would be admissible for litigation purposes regardless of dissemination through normal scientific channels; and there are powerful incentives to refrain from formal written presentation or publication outside the legal arena, because such restraint reduces both the material available for cross-examination and the risk of professional refutation (as well as professional embarrassment). Petitioners' view thus would predictably foster a separate world of "litigation science."

2. In-Court Assessment of a Claim for Conformity to Accepted Standards Is Otherwise Necessary to Establish a Foundation.

The accepted scientific standards for testing *some* scientific propositions for validity do not require passage through the process of community dissemination, scrutiny,

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[23] *Amici* cite as an example the "resistance" to a theory of electrical communication by the nerve systems of plants. Br. 15. Even aside from the nature of the source relied on—a newspaper account, quoting the participants, with their natural inclination to portray the "human story" as one of a lonely fight for recognition against closed minds—there is nothing in this example to suggest that anything occurred other than the natural process of scientists insisting that "revolutionary" theories prove themselves by solid evidence. Not even *amici* suggest that the proponents of the new theory had such evidence before they announced what *amici* themselves call their "discovery" (*id.* at 15).

Indeed, one of petitioners' *amici* has aptly written elsewhere: "A man cannot wear the mantle of Galileo simply because he stands against the establishment that treats him badly: he must also be right, or at least brilliant." S.J. Gould, *Zealous Advocate*, 176 Science 623, 625 (1972) (book review).

and verification. Thus, a case-specific diagnosis of an individual patient; a generalization that is so narrow as to be of no interest to available publications, means of communication, or other scientists; or a newly discovered claim that there has been no time to submit for community scrutiny in any formal way—these would, by dint of necessity, not be disqualified from having an adequate foundation by failure to pass through the normal community processes. In these situations, the foundational validity required by Rule 702 can be judged only by an in-court assessment of the evidence and reasoning offered in support of the claim, measured against accepted standards for validating that kind of claim. Indeed, where the underlying data are themselves inadmissible, Rule 703 by its express terms independently requires just such a determination, insisting that the grounds for the claim be "of a type reasonably relied on by experts in the particular field in forming opinions or inferences upon the subject."

This in-court inquiry into the sufficiency of the foundation for expert opinion testimony necessarily has two components: (1) the proper materials must be used—where bricks are required, sawdust will not do; and (2) those materials must be used in a reasonable fashion—although bricks may be a proper component in constructing a house, bricks alone, without mortar, are insufficient to sustain the structure. The foundational requirement thus demands inquiry not only into the raw data relied on by an expert, but also into the processes used to develop and integrate those data before an opinion may properly be based on it. Indeed, the Advisory Committee Note to Rule 703 emphasizes this point by reference to "public opinion poll evidence," as to which courts are instructed, in determining admissibility, to direct their attention "to the *techniques employed*" (emphasis added) —that is, not just to the fact that the expert is relying on responses of people surveyed, but also to the sampling methodology, including the size of the sample, the ques-

tions asked, the responses counted or not counted, etc. It was just such an analysis that was undertaken by the case cited in the Advisory Committee Note as a model, *Zippo Mfg. Co. v. Rogers Imports, Inc.*, 216 F. Supp. 670 (S.D.N.Y. 1963). *See also United States v. Esle*, 743 F.2d 1465, 1474 (11th Cir. 1984) (rejecting expert opinion under Rule 703 based on untrustworthy market survey).[24]

Ignoring the inescapable relationship between Rules 702 and 703 (*see* pp. 18-19, *supra*), petitioners fasten only on the language in the latter rule providing that the "facts or data" used by an expert need not be admissible in evidence if they are "of a type reasonably relied upon by experts in the field." According to petitioners, this means that as long as an expert uses "data that scientists generally rely upon in formulating an opinion," the opinion must be admitted regardless of the expert's methods or reasoning process. Pet. Br. 37. This isolated parsing of the words of Rule 703 demonstrates how nonsensical petitioners' reading of the Rules is.[25] Thus, in

[24] This approach has repeatedly been followed by the lower federal courts in determining the admissibility of scientific testimony in numerous areas. *See, e.g., Head v. Lithonia Corp.*, 881 F.2d 941, 943 (10th Cir. 1989) (expert opinion that plaintiff suffered from head injury, which is based on topographical brain mapping, is inadmissible because this technique is not generally relied on by others in the field); *Viterbo v. Dow Chemical Co.*, 826 F.2d 420, 422-23 (5th Cir. 1987) (reliance on incomplete family history bars opinion on causation of injury); *Barrel of Fun, Inc. v. State Farm Fire & Casualty Co.*, 739 F.2d 1028, 1033 (5th Cir. 1984) (expert cannot base opinion on voice stress analysis); *United States v. Trunowski*, 659 F.2d 750, 755 (7th Cir. 1981) (even though sun charts generally relied on by experts in the field, use of chart for purpose of rendering opinion on date of photographs is prohibited because "chart had never been verified in usage for th[at] particular purpose").

[25] Petitioners go so far as to suggest that expert testimony would be admissible even if it were based on facts or data *not* reasonably relied on by experts in the field, as long as the expert personally observed the data. This conclusion follows directly from petitioners'

petitioners' view, if their experts took the numbers in an epidemiological study, put them into a computer, and repeatedly pushed "randomize," the experts could then base their opinion on the results of any one of those outcomes that they chose. Similarly, if they took a published study, relied on the helpful data and arbitrarily excluded the unhelpful data, they could then testify to an opinion based on their biased selection of the data. We doubt that Congress intended to countenance such results.[26]

C. Petitioners' Proffered Expert Testimony Doubly Fails To Meet The Necessary Foundation Requirement.

Petitioners must prove by a preponderance of the evidence that Bendectin caused their limb defects. To establish that case-specific claim, in the face of the uniformly negative epidemiological studies on Bendectin's properties in this regard, petitioners could not and do not rely on mere anecdotal, unsystematic medical opinion. Rather, they must and do offer expert scientific testimony to a general proposition about Bendectin's intrinsic properties —that the medication causes limb defects in babies who otherwise would not suffer them.[27]

reading of Rule 702 coupled with their principal reading of Rule 703, which they claim "provides no textual support for placing special limitations on expert testimony." Pet. Br. 35.

[26] The illogic of petitioners' "data-base" interpretation of Rule 703 is further demonstrated by a distinction that even petitioners feel constrained to draw. At one point in their argument, petitioners acknowledge that "it is plausible to argue" that an expert opinion in a Bendectin case based on "the alignment of the planets" would be inadmissible under Rule 703. Pet. Br. 37 n.66. But there is no substantive difference between an expert who looks to the planets when his or her gaze should be earthbound and one who is properly looking skyward in order to count the planets but concludes that the number is seven by inexplicably refusing to count Jupiter and Saturn. Opinions based on either ground are equally lacking in foundation under accepted scientific standards and are equally inadmissible.

[27] More particularly, as discussed below, petitioners must establish an increased rate of limb defects high enough to support the

Both courts below found, in accord with four other federal circuits, that accepted scientific standards do not allow an inference that Bendectin caused petitioners' limb reduction defects to be drawn based on the data and reasoning used by petitioners' experts. Thus, in addition to the inadmissibility of the general propositions about Benedectin's inherent properties in the absence of community scrutiny and verification, petitioners' crucial expert testimony was also inadmissible because of the aberrant and unreliable mode of reasoning by which they reached their necessary ultimate conclusion.

1. *Petitioners' Novel Claim about Bendectin's General Properties, Contradicting Uniform Published Analyses, Cannot Be Validated Without Passage Through the Normal Channels of Communication for Scientific Community Scrutiny and Verification.*

The generalization that Bendectin causes human limb defects is a classic empirical generalization, validated only through the process of community scrutiny. Any claim to this effect necessarily must include careful statistical analyses of large volumes of data, or at least arguments about the propriety of drawing inferences from animals to humans in the face of massive human data. Any such analyses and arguments must be carefully examined and criticized by others in the field. And a new conclusion like that offered by petitioners' experts, even if facially plausible, must be tested not only against a mountain of available evidence but against new studies designed to resolve any apparent conflict.

Yet none of petitioners' experts has ever set out in writing the data, premises, and methodology leading to the suggested conclusion: they have not submitted to community scrutiny through normal scientific channels,

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inference that, absent any other information, it is more likely than not that Bendectin, rather than another (unknown) agent, was the cause of the limb defects of any particular child whose mother took Bendectin.

much less gained independent acceptance for, an analysis purporting to explain the basis for concluding that Bendectin causes human limb reduction defects. The experts who rely on non-human evidence have never written and submitted for community scrutiny an argument that a legitimate inference of human causation can be drawn based on such evidence. And the experts who rely on human epidemiological evidence have never written up and disseminated their statistical analyses, along with an argument justifying the conclusions they base on the analyses and explaining why they think the published literature is wrong.

Nor can any of these experts claim a valid excuse: these are not brand new discoveries, too fresh to publish; these are not narrow claims of little interest to available publications or to other scientists. On the contrary, the topic is among the most thoroughly researched and publicized in the relevant scientific fields. In these circumstances, failure to submit formally reasoned papers making this claim to the normal channels of peer communication, aside from suggesting that the claims could not withstand community scrutiny, leaves the claim without an adequate foundation in the methods scientists themselves use to validate such claims. The expert testimony is therefore inadmissible.[28]

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[28] On this record, the only published work concerning Bendectin and birth defects by any of petitioners' experts is a one-paragraph "abstract" published by Dr. Swan. That is patently inadequate to establish a foundation, and the reason is worth stressing. Dr. Swan nowhere set out her assumptions or reasoning in the abstract; yet when one key assumption was later examined in *Lynch*, *supra*—using as the control group, not the entire universe of non-Bendectin users, as the Centers for Disease Control had done, but instead children affected with Down's syndrome and other genetic disorders—it was found unwarranted and misleading. 830 F.2d at 1195. An unelaborated report of a reanalysis is no basis for the scientific community even to begin the process of scrutiny and verification of how the reanalysis was done—what data were used, how they were classified, what statistical techniques were used, what inferences are

2. *The Claim of Petitioners' Experts Cannot Be Validated, Under Accepted Scientific Standards, by the Types of Data and Methodology They Use.*

The testimony of petitioners' experts is inadmissible for another reason as well. The experts rely on animal studies, chemical structure analyses, and unpublished "reanalyses" of other scientists' epidemiological studies to support their conclusion that "Bendectin is a human teratogen." Pet. Br. 4. Given the vast body of published epidemiological studies on the relationship between Bendectin and birth defects, however, these other materials are *not* "of a type reasonably relied upon" by experts in the field. As the Ninth Circuit correctly concluded, "the available animal and chemical studies, together with [petitioners'] expert reanalysis of epidemiological studies, provide insufficient foundation to allow admission of expert testimony to the effect that Bendectin caused [petitioners'] injuries." J.A. 241; *cf. id.* at 234-35 (district court) ("expert opinion which is not based on epidemiological evidence is not admissible to establish causation because it lacks [a] sufficient foundation").

a. At the outset, it is important to stress the specific nature of petitioners' burden of proof here—causation of their own injuries by Bendectin under a preponderance standard. Petitioners ignore this point and rely instead

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asserted based on the analysis, how those inferences fit with other available evidence—and whether the conclusion drawn is warranted. *See* J. Casti, *Paradigms Lost* 61 (1989) ("Science is defined in terms of *how* and *why* we know something, not *what* we know. . . . What makes a theory a serious contender is not just the theory, but the theory plus the arguments that support it.").

We note that, after summary judgment was granted in this case, petitioners' expert, Dr. Newman, published a letter to the editor in the Journal of the American Medical Association. 264 J. Amer. Med. Ass'n 569 (Aug. 1, 1990). That letter, of course, is not part of the record on summary judgment. But even that letter purports to do no more than describe certain non-epidemiological studies; it does not make any argument for an inference based on such studies, much less an argument that explains away the massive epidemiological evidence.

on government and scientific publications stating that animal data are sufficient grounds for deciding *other* issues, such as whether to keep a product off the market, to engage in further research, or to recommend harmless and inexpensive protective measures. *See, e.g.*, Pet. Br. 5. But these uses of animal evidence are all quite different from the use needed to support the claim of causation at issue here.[29]

Thus, in deciding whether to keep a new product off the market, there is no suggestion that the government is making a "more-likely-than-not" retrospective determination. On the contrary, any non-frivolous cause for concern may be sufficient for this purpose: even a quite small likelihood of toxicity might readily justify delaying (for further research at least) the introduction of such a product.[30] Indeed, in making a prospective determina-

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[29] The affidavit of petitioners' expert Dr. Swan illustrates this point. Using the form of the double negative, she states that "one cannot draw a conclusion from [the epidemiological studies] that Bendectin does not cause limb reduction defects." She then states: "when there is data consistent with increased risks, as with Bendectin, [we should] conclude that it is more probable than not that Bendectin is associated with birth defects." J.A. 116. But "data consistent with increased risks" includes everything but conclusive demonstration of no increased risk. Her reasoning therefore transforms a mere possibility into a 50% probability.

More generally, petitioners are attempting to take the premise that epidemiology is not a powerful enough tool to disprove the mere *possibility* that Bendectin (or any other drug) is a teratogen at some very low level, and to leap from that basis to the conclusion that Bendectin is a teratogen at more than a doubling level (*see* p. 40, *infra*). This is but another form of unjustified reliance on animal and chemical studies to prove much more than they are capable of proving, not only using them to shift the epidemiological burden of proof, but also to magnify the significance of epidemiology's inability to disprove a negative conclusively.

[30] *See* Amer. Soc. Law, Medicine & Ethics *Amicus* Br. 2-3, 4 ("the purposes and processes of regulatory agency proceedings, aimed at prospective risk elimination, differ sufficiently from retrospective jury damages trials and . . . the same evidentiary standards would not apply"; "Where the question is whether . . . there is a

tion of risk, animal data and chemical analyses will often be the *only* information that experts can rely on: until a product is brought to market, extensive human data will almost never be available. Petitioners' approach, in short, ignores the obvious fact that a foundation admittedly strong enough to support a hundred-pound weight does not *ipso facto* support a thousand-pound weight.

Given the present state of scientific knowledge, moreover, when it comes to a "more-likely-than-not" causation requirement with respect to limb defects, the fact is that petitioners are seeking to shoulder a heavy burden indeed. As the Fifth Circuit has aptly observed, "[a]ssuredly, one day in the future, medical science may have a clearer understanding of the mechanics of tissue development in the fetus. However, that is not the case today." *Brock*, 874 F.2d at 315. It is undisputed that "[i]n ninety-five percent of the cases of limb reduction . . . the cause is unknown." *Lynch*, 830 F.2d at 1193 (citing testimony of petitioners' expert here, Dr. Alan Done, and of Dr. Murray Feingold, Physician-in-Chief at the National Birth Defects Center). On the other hand, it is likewise undisputed that the overwhelming majority of women that used Bendectin did *not* give birth to children with limb reduction.

These undisputed facts mean that direct proof of causation in a birth defect case is impossible: experts can rely only on circumstantial proof through statistical inference. And when that kind of evidence is advanced to satisfy a more-likely-than-not burden of proof requirement, a plaintiff can carry the burden only by showing that the odds are at least *twice as great* that a woman who takes Bendectin will have a child with a limb defect than a woman who does not take the drug. *See DeLuca*, 911 F.2d at 958 ("to avoid summary judgment, the rela-

risk of harm from a particular chemical exposure, the range of relevant, admissible scientific evidence might, under Rules 702 and 403, be broader than where the issue is one of actual causation related to a particular individual's injury.").

tive risk of limb reduction defects arising from the epidemiological data [an expert] relies upon will, at a minimum, have to exceed '2' "). *See* Comment, *Causal Inference in Epidemiology: Implications for Toxic Tort Litigation*, 71 N.C. L. Rev. 247, 280-85 (1992).

b. In finding petitioners' foundation wanting, both courts below rested essentially on two conclusions: (1) that *only* human data could provide a reasonable basis for an opinion that Bendectin caused petitioners' injuries; and (2) that the human data relied on by petitioners' experts were not of a "type reasonably relied upon" in answering that question. We address each point separately and show that both are correct.[31]

i. To begin with, the district court correctly ruled that "[a]bsent a scientific understanding of the cause of the birth defects at issue in Bendectin cases, causation may be shown only through reliance upon epidemiological [human] evidence." J.A. 230 (citing *Richardson; Lynch; In re Agent Orange Prod. Liab. Litig.*, 611 F. Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987)); *see also* J.A. 239 (court of appeals). There is virtually universal consensus in the field of teratology that human data are needed to show causation—in contrast to mere risk (*see* pp. 38-40, *supra*). In fact, according to current authorities, more than 1200 substances are considered to be animal teratogens, while only 30 substances are known human teratogens. *See* Shepard, *Catalog of Teratogenic Agents*, p. xiii (7th ed. 1992). Consequently, it is well recognized that "[e]xperimental work with animals can be suggestive, but never conclusive, that a drug may be tera-

[31] The Ninth Circuit reviewed the district court's conclusion that petitioners' causation evidence was inadmissible under a *de novo* standard. J.A. 238-39. Since the district court had ruled for respondent, that review standard is more advantageous to petitioners than more deferential ones like abuse-of-discretion. If, as we argue, the Ninth Circuit's ruling was correct, there is no need here to decide whether a more deferential standard of appellate review is warranted.

togenic to humans. In human populations, we are limited to what can be learned by means of epidemiological methods." Heinonen, Slone, & Shapiro, *Birth Defects and Drugs in Pregnancy* 6 (Wright 1983).

Even many of petitioners' experts agree with this view. For example, in *Richardson*, Dr. Done, who has aptly been characterized as "the primary causation expert [for plaintiffs] in numerous [Bendectin] cases" (*DePyper v. Navarro*, No. 83-303-467, slip op. 25 (Mich. Cir. Ct. June 13, 1989); *see* J.A. 230-33), testified that " 'before you can make a conclusion that a substance is teratogenic in humans, you must look to the human data' " (857 F.2d at 830 (citing Tr. 1104)); more specifically, " 'you would not give an opinion as to causation without a statistically significant association in humans between the ingestion of a drug and a cause of birth defects' " (857 F.2d at 831).[32] Similarly, in *Brock*, Dr. Glasser, also one of petitioners' experts here, "admitted that the only way to tell whether a substance is teratogenic in humans is to look to the human experience." 874 F.2d at 314. And to the same effect, Dr. Palmer, another of petitioners' experts here, testified in his deposition in this case, "I don't make an extrapolation from nonhuman animals to humans . . . Those discussions are without value." Palmer Dep., Tr. 443. *See generally*, *Lynch*, 830 F.2d at 1194 ("*in vivo* animal studies, *in vitro* animal studies, and the study of 'analogous' chemicals . . ., singly or in combination, do not have the capability of proving causation in human beings") (citing district court decision at 646 F. Supp. at 865-66, detailing numerous examples of plaintiffs' expert testimony to this effect).[33]

It is hardly surprising, therefore, that all five circuits to have ruled on the issue have held that animal data and chemical analyses are not a proper foundation on which to rest a conclusion that Bendectin causes limb defects in humans. And in the sixth case, *DeLuca*, the plaintiffs themselves deemed the contention so insubstantial that they did not challenge the district court's ruling (following the magistrate) barring the admission of such evidence. 911 F.2d at 946 n.8. In short, as Judge Weinstein explained in a landmark decision in this area, "sound epidemiological studies . . . are the only useful studies having any bearing on causation" in a toxic tort case. *In re "Agent Orange" Product Liab. Litig.*, 611 F. Supp. at 1231.

Not surprisingly, given this formidable body of precedent, petitioners nowhere argue that the non-epidemiological evidence is a sufficient basis for their experts' testimony. Instead, they attempt to support their conclusions by aggregating these bases with the admittedly insufficient human data. Pet. Br. 6-12. But this attempt

[32] Petitioners stress the controversy some epidemiologists have raised about the standard use by epidemiologists of a 95% confidence level as a condition of statistical significance. Pet. Br. 8-10. *See also* Rothman *Amicus* Br. It is hard to see what point petitioners' discussion establishes that could help their case.

Petitioners' experts have never developed and defended a detailed analysis of the epidemiological data using some alternative well-articulated methodology. Nor, indeed, do they show (or could they) that with some other plausible measure of confidence (say, 90%) the many published studies would collectively support an inference that Bendectin caused petitioners' limb reduction defects. At the very most, all that petitioners' theoretical speculations do is question whether these studies—as the medical profession and regulatory authorities in many countries have concluded—affirmatively prove that Bendectin is *not* a teratogen. But that is hardly a help to petitioners, because it is they who have the burden of proof.

[33] Petitioners' reliance on so-called "chemical structure" analyses is likewise misguided. As the courts of appeals generally have found, this kind of analysis has no power in the face of strong epidemiological data demonstrating no human effect. *See, e.g.*, *Richardson*, 857 F.2d at 829-30. Even on their own terms, petitioners' chemical analyses are useless because they compare Bendectin not to a substance "known to cause limb reduction birth defects" (Pet. Br. 7), but to a substance (an antihistamine) about which, in the words of petitioners' expert Dr. Done, at most a " 'suspicion' " has been raised. *Richardson*, 857 F.2d at 830. This pyramiding of speculations does not add up to probative evidence.

to prove causation by cumulating two insufficient kinds of facts or data must fail: it cannot produce a foundation that is reasonably relied on to establish the requisite opinion testimony here.

The animal data, as we have said and as petitioners' own experts indicate, can point to areas of possible risk and thus directions for further reasearch. But when that further research is strongly negative, it is unreasonable to add the animal studies that provoked the research to the negative conclusions resulting from it and come out to a positive conclusion. In short, the only proper foundation for the causation finding at issue here is human data. That is precisely what petitioners' expert, Dr. Done, has testified to—"you could not give an opinion as to causation without a statistically significant relationship in *humans*" (*Richardson*, 857 F.2d at 831 (emphasis added))—and to the extent that petitioners' expert opinions do not rest on such a foundation, they cannot be adequately propped up by animal data and chemical analyses.

ii. Turning then to the human data relied on by petitioners' experts, we begin by noting that of the eight experts proffered by petitioners (*see* Pet. Br. 2-3 & n.5; J.A. 232), only *one*, Dr. Palmer, is prepared to offer the opinion that "Bendectin did cause the limb defects in each of the [petitioners]." J.A. 192. The others conclude (at most) only that "there is a statistical *association* between Bendectin and limb defects." J.A. 152 (Glasser) (emphasis added); *see, e.g.*, J.A. 117 (Swan: "Bendectin is associated with birth defects, including limb defects"). But this latter conclusion—even if repeated numerous times—cannot support a jury verdict for petitioners. *See* pp. 40-41, *supra*. As the Sixth Circuit recently pointed out, "plaintiffs' experts stop short of testifying that Bendectin more probably than not caused the birth defects in babies. They have no factual or theoretical basis for a stronger hypothesis." *Turpin*, 959 F.2d at 1359-60.

Consequently, in our view, petitioners' submission here ultimately stands or falls with Dr. Palmer's testimony. But the bases for his testimony are self-evidently insufficient to support its conclusion. He claims that, in forming his opinions, "I have reviewed various *pieces* of scientific data and literature pertaining to Bendectin. I have specifically reviewed what I believe to be *all of the animal studies pertaining to Bendectin*." J.A. 190 (emphasis added). But no expert, "when not in court" (Rule 703, Adv. Comm. Note), would rely on that admittedly incomplete set of facts and data to formulate the opinion that Dr. Palmer is prepared to offer. Beyond that, while Dr. Palmer does not even indicate what epidemiological data he looked at, he nevertheless opines that "epidemiological data is the *least* reliable [in determining whether Bendectin is a teratogen]." J.A. 191 (emphasis added). These statements indicate that the available epidemiological data, which Dr. Palmer acknowledges not having thoroughly researched, played little, if any, role in forming his opinion; and he plainly did not rely on any data showing a statistically significant relationship between Bendectin and limb defects in humans.

That foundation cannot reasonably support the opinion that Bendectin causes limb defects, much less the more demanding opinion that Dr. Palmer offers—that these two petitioners' defects were caused by Bendectin. As the Sixth Circuit recently ruled in a case where Dr. Palmer offered essentially the same testimony: "the evidence cited in support of [Dr. Palmer's] conclusion is insufficient to meet the plaintiffs' burden of proof. Dr. Palmer does not testify on the basis of the collective review of his scientific discipline, nor does he take issue with his peers and explain the grounds for his differences. *Indeed, no understandable scientific basis is stated.* Personal opinion, not science, is testifying here." *Turpin*, 959 F.2d at 1360 (emphasis added). *See also Cadarian v. Merrell Dow Pharmaceuticals, Inc.*, 745 F. Supp. 412 (E.D. Mich. 1989) ("Dr. Palmer has failed to cite facts or data of a type reasonably relied upon by experts in his

field in support of the opinion that Bendectin was a proximate cause of [plaintiffs'] birth defects").[34]

Moreover, even if petitioners' other expert testimony, claiming merely that Bendectin is "associated with limb defects," could suffice to raise a triable issue on causation (*but see* p. 44, *supra*), petitioners would still lack admissible evidence: those less ambitious opinions likewise do not rest on an adequate epidemiological foundation. Both in this Court and in the district court, petitioners focus in this regard solely on Dr. Glasser's opinion, presumably because, in their view, his opinion is most reliably based on the epidemiological data. Pet. Br. 7 & nn. 21-25; Plaintiffs' Opp. To Defendants' Motion for Sum. Judg. at 19. But his proposed testimony, much like that of his colleagues, simply does not rest on facts or data "reasonably relied upon by experts in the . . . field."[35]

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[34] Dr. Palmer claims that he examined the medical records of petitioners' mothers' in reaching his conclusions. J.A. 192. But all he concludes from this "examination" is the undisputed fact that these women took Bendectin during the early months of their pregnancy. That fact, of course, says nothing about whether Bendectin *caused* the defects.

[35] As the district court's opinion in this case indicates (J.A. 230-31), petitioners relied in part on Dr. Alan Done to provide a "reanalysis" of the epidemiological data. (Petitioners originally listed him as a witness; subsequently withdrew his name and substituted Dr. Palmer; but then attached some of Dr. Done's testimony in another case to their opposition to summary judgment.) Yet petitioners barely mention Dr. Done in this Court. *See* Pet. Br. 5 n.9.

The reason is evident: Dr. Done and the substance of his testimony have both been thoroughly discredited. As to Dr. Done, the trial court in *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 563 A.2d 330 (D.C. 1989), *cert. denied*, 493 U.S. 1074 (1990), found after an evidentiary hearing that Dr. Done "knowingly and intentionally gave false testimony at trial in six areas . . . related to his qualifications." *Id.* at 332. *But cf. id.* at 333-38 (ruling that any misrepresentations were insufficient to allow a new trial on a Rule 60(b)(6) motion). As to his testimony, the district court on remand in *DeLuca* found that Dr. Done's calculations were riddled

Thus, Dr. Glasser simply takes three of the numerous epidemiological studies that have been conducted and notes his disagreement with the researchers who found no statistically significant relationship between Bendectin and limb defects. He apparently bases this disagreement on the fact that these researchers used the customary 95% confidence level to determine statistical significance. But there are two problems that make this reliance unreasonable. First, Dr. Glasser accounts for only a tiny portion of the available epidemiological data, providing no reason as to why he rejects the numerous other studies. No responsible scientist relies on that kind of preselected data alone. *See, e.g.*, EPA, Proposed Guidelines For Assessing Male Reproductive Risk, 53 Fed. Reg. 24850, 24860 (June 30, 1988) ("[a]ll relevant data should be considered in risk assessments"). This is precisely the kind of "data dredging" that the Advisory Committee Note indicates violates the proscriptions of Rule 703. See pp. 33-34, *supra*. Second, although Dr. Glasser rejects the customary 95% confidence level generally relied on by scientists in this field (*see DeLuca*, 911 F.2d at 947-48,[36] he fails to provide, much less support the use of, some alternative standard. *See* note 32, *supra*. All that Dr. Glasser has done is to look for the highest Bendectin-correlation numbers in the array of epidemiological data and then conclude, *ipse dixit*, that "there is in fact a statistical association between Bendectin and birth defects including limb defects." J.A. 152. Teratologists, we submit, do not rely on that jury-rigged data base to reach

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with error, often incomprehensible, and downright misleading. *DeLuca*, 791 F. Supp. at 1047-54. *See also Lynch*, 830 F.2d at 1196 (rejecting Dr. Done's reanalysis); *Richardson*, 857 F.2d at 830-31 (same).

[36] Although the Third Circuit views the use of this level as "arbitrary," it nevertheless acknowledges that a 95% confidence level is a "common value on the tables scholars use to calculate significance" (911 F.2d at 947) and a "convention of [the epidemiology] discipline" (*id.* at 948).

the opinion put forth by Dr. Glasser. *See Brock*, 874 F.2d at 312 (similarly rejecting Dr. Glasser's epidemiological analysis).[27]

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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[27] Even if this Court adopts petitioners' view of the Rules and holds the evidence at issue admissible, the judgment below should still be affirmed. At a minimum, the foregoing analysis demonstrates that petitioners' evidence on the question of causation is simply insufficient, against the weight of respondent's scientifically validated and formally reviewed epidemiological evidence, to support a rational verdict finding causation. No materially different analysis being required, this is a proper alternative ground (argued below) in support of summary judgment. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986).

APPENDIX

FEDERAL RULES OF EVIDENCE

Rule 102. Purpose and Construction

These rules shall be construed to secure fairness in administration, elimination of unjustifiable expense and delay, and promotion of growth and development of the law of evidence to the end that the truth may be ascertained and proceedings justly determined.

Rule 104. Preliminary Questions

(a) Questions of admissibility generally. Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

(b) Relevancy conditioned on fact. When the relevancy of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition.

(c) Hearing of jury. Hearings on the admissibility of confessions shall in all cases be conducted out of the hearing of the jury. Hearings on other preliminary matters shall be so conducted when the interests of justice require, or when an accused is a witness and so requests.

(d) Testimony by accused. The accused does not, by testifying upon a preliminary matter, become subject to cross-examination as to other issues in the case.

(e) Weight and credibility. This rule does not limit the right of a party to introduce before the jury evidence relevant to weight or credibility.

Rule 401. Definition of "Relevant Evidence"

"Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.

Rule 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible

All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Rule 403. Exclusion of Relevant Evidence on Grounds of Prejudice, Confusion, or Waste of Time

Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

Rule 602. Lack of Personal Knowledge

A witness may not testify to a matter unless evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter. Evidence to prove personal knowledge may, but need not, consist of the witness' own testimony. This rule is subject to the provisions of rule 703, relating to opinion testimony by expert witnesses.

Rule 701. Opinion Testimony by Lay Witnesses

If the witness is not testifying as an expert, the witness' testimony in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness and (b)

helpful to a clear understanding of the witness' testimony or the determination of a fact in issue.

Rule 702. Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Rule 703. Bases of Opinion Testimony by Experts

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Rule 803. Hearsay Exceptions; Availability of Declarant Immaterial

The following are not excluded by the hearsay rule, even though the declarant is available as a witness: . . .

(18) Learned treatises. To the extent called to the attention of an expert witness upon cross-examination or relied upon by the expert witness in direct examination, statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. If admitted, the statements may be read into evidence but may not be received as exhibits.

Supreme Court, U.S.
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No. 92-102

IN THE

Supreme Court of the United States

October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, INDIVIDUALLY AND AS GUARDIANS AD LITEM FOR JASON DAUBERT, AND ANITA DE YOUNG, INDIVIDUALLY AND AS GUARDIAN AD LITEM FOR ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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Jack B. Weinstein, *Rule 702 of the Federal Rules of Evidence is Sound; It Should Not Be Amended*, 138 F.R.D. 631, 636 (1991) 7
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REPLY BRIEF OF PETITIONERS

Some of the central points in our opening brief have been conceded and/or confirmed by the briefs of Merrell and *amici curiae*:

1. A wide spectrum of *amici curiae* agrees that the "general acceptance" (or *Frye)* test applied by the Ninth Circuit in this case is not a proper interpretation of the Federal Rules of Evidence ("FRE"). *See, e.g.*, the briefs of the United States ("U.S. Br.") 17-18, the Group of American Law Professors ("Law Profs. Br.") 5-7, the Carnegie Commission 7-9, the American College of Legal Medicine 7-8, and the American Medical Association ("AMA Br.") 9. Even Merrell, while paying brief lip service to the *Frye* test (Resp. Br. 25-26), proffers as the *correct* interpretation of the FRE a test that differs from the one applied by the courts below (*id.* 12-24, 27-35). In short, the rationale on which the Ninth Circuit relied is defended by nothing more than a fig leaf, and the answer to the first question presented is — almost by default — "no."

2. Briefs filed by several scientific organizations confirm that the Ninth Circuit also erred in holding that scientists generally do not accept and rely upon reanalyses of epidemiological data unless they have been published and peer reviewed.[1]

3. No one has challenged petitioners' contention that California courts would admit the testimony of petitioners' experts and find it sufficient (as the District of Columbia Court of Appeals found it sufficient, *see* Pet. Br. 42) to support a jury

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[1] *See* Brief of Physicians, Scientists and Historians ("Physicians Br.) 4, 16-19; Brief of American Society of Law, Medicine & Ethics ("ASLME Br.") 10, 17-20; Brief of Kenneth Rothman *et al.* 12-13; Carnegie Commission Br. 25-28. *See also* Brief of Alvin R. Feinstein 8-10. The unreliability of publication and peer review as criteria for assuring scientific rigor, and the relative advantages of cross-examination for that purpose, are described in Brief of Daryl Chubin *et al.* 12, 18-24, 28-30. See also other concessions in the briefs of *amici* supporting Merrell: Brief of American Association for the Advancement of Science *et al.* 16, 21; AMA Br. 17; Brief of Nicolaas Bloembergen *et al.* 8-10; Brief of New England Journal of Medicine 3, 5, 11, 15.

finding of causation. The description of each State's rules in the brief of Texas *et al.* ("States' Br.") 5-9, suggests that the testimony would be admissible in at least 45 and possibly all 50 States. This highlights the federalism issue posed when the FRE are applied, as they were by the courts below, to distort the outcomes of state tort suits by excluding evidence the State deems sufficient to trigger its compensatory tort mechanisms.

We respond below to the matters which *are* contended in the briefs of Merrell and its supporting *amici*.

I. MISCHARACTERIZATIONS OF THE RECORD BY MERRELL AND ITS *AMICI*

This case does not involve "junk science." The experts whose testimony was proffered by petitioners are highly credentialed scientists, some of whom hold important governmental posts; their principal occupation consists of making probabilistic determinations of whether particular substances cause injuries observed in the population. For several decades Adrian Gross has been a high-level official of both the FDA and the EPA, responsible for making probabilistic determinations of causation upon which those agencies rely. Jay Glasser is the *court-appointed* epidemiological expert on causation in the Dalkon Shield litigation. Shanna Swan is the chief epidemiologist for a major department of the State of California. Stewart Newman is one of the nation's leading experts on the formation of the human limb. Pet. Br. 3 n.5.

These experts did not arrive at their opinions by reading tea leaves[2] or by instructing a computer to randomize the raw numbers in Bendectin studies done by others.[3] Rather, as their testimony explains in elaborate detail,[4] they applied well-established methodologies that scientists customarily employ — indeed, that they themselves employ in their daily scientific work

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[2] A hypothetical discussed in Law Profs. Br. 14.

[3] A hypothetical discussed in Resp. Br. 35.

[4] For each of these witnesses, the record contains hundreds of pages of testimony detailing the methodology by which they reached their ultimate conclusions. See Tabs 12, 21, 26, 32, cited in Pet. Br. 3 n.4.

advising their governmental employers — to assess the likelihood that Bendectin causes human limb defects. Pet Br. 5. The methods employed by petitioners' experts[5] are precisely the methods routinely employed by scientists, indeed, prescribed by federal regulations, to assess the probability that a particular drug is causing observed injuries.[6]

No evidence was introduced below *disputing* that the methodologies of these scientists were those customarily employed by scientists investigating causation. The district court's opinion in this case recites that Swan's opinion is based on "the methodology . . . generally and reasonably relied upon by epidemiologists . . . in trying to draw opinions concerning whether or not there is a cause and effect relationship between a drug and a birth defect" (J.A. 233 (quoting Swan Aff. at 7-8)), and that Glasser's opinion rests on "techniques that are generally and reasonably relied upon by biometrists, epidemiologists, and biostatisticians." J.A. 234. The disagreement between petitioners' and Merrell's experts is not in their methodologies, but in the conclusions they have reached upon appraising evidence gathered through a common methodology.

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[5] The methodology these experts employed was to examine the results of *in vivo* studies documenting the effect of Bendectin on animals, to analyze the results of *in vitro* microscopic examinations of cells exposed to Bendectin, to analyze the chemistry of Bendectin in light of knowledge of the effect of similar chemicals upon human limb birth defects, to analyze the data collected in the various attempts to survey the effect of Bendectin on humans (*i.e.*, the epidemiological data), and from the entirety of this data to evaluate the likelihood that Bendectin causes human limb defects. Pet. Br. 4-6.

[6] The applicable regulations are described in ASLME Br. 10-20. A 1991 EPA Guideline declares that "[i]n almost all cases, experimental animal data are predictive of a developmental effect in humans." *Id.* 12. Ideally, evidence regarding the effect on humans would be the best data, but federal agencies have found that limitations in the ability to derive epidemiological data have made such data a relatively unreliable predictor for most substances. *Id.* 14-16. In consequence, the accepted scientific approach is to examine, evaluate and integrate all available animal, chemical and epidemiological data. *Id.* 11-13, 16-17. The absence of statistically significance indices of causation is *not* regarded as conclusive. *Id.* 14-16.

Merrell suggests that the epidemiological evidence "demonstrat[es]" the safety of Bendectin. Resp. Br. 43 n.33. This is not accurate. The correct formulation is the one in Merrell's initial description of the epidemiological evidence: "no published study has found any *statistically significant* association between Bendectin and the sort of birth defects (limb reduction) at issue here." Resp. Br. 4 (emphasis added). The *amicus* briefs of many scientists corroborate the testimony of petitioners' experts that epidemiological evidence not meeting *95 percent* statistical significance may still be probative of causation, and assuredly does not demonstrate the *absence* of causation.[7] Indeed, even the district court recognized that the epidemiological evidence here leaves it "possible" that there was causation (J.A. 236), though that court ruled the evidence insufficient to sustain plaintiffs' burden of going forward because it thought statistical significance was required as a matter of law. J.A. 235-36.

The authors of the most "dramatic" (Resp. Br. 4) epidemiological study relied upon by Merrell, after stating their conclusion that a meta-analysis of the epidemiological evidence did not show an association between Bendectin and human birth defects, acknowledged that this finding should be a "relatively minor" factor in the overall assessment of whether Bendectin causes birth defects.[8] These authors explained:

> Meta-analysis of Bendectin teratogenicity studies [i.e., epidemiological studies] . . . alone should not be the sole determinant of whether a particular compound can be used safely in pregnancy. Instead, such a decision should be based on all available information, including *in vitro* data, and animal teratogenicity testing, as well as a good measure of common sense, particularly when considering the

[7] Rothman Br. 3-8; ASLME Br. 14-16; Carnegie Commission Br. 22 n. 29; Physicians' Br. 12-13; Feinstein Br. 12-16.

[8] Einarson, *et al.*, *A Method for Meta-Analysis of Epidemiological Studies*, 22 Drug Intelligence and Clinical Pharmacy 813, 822 (1988). In any event, the method employed in this study has been criticized by one of Merrell's *amici* as a "highly controversial procedure" that goes well beyond mixing apples and oranges, and is more like mixing a "fruit salad" with a "garden salad, shrimp salad, and pasta salad." Feinstein Br. 10.

> temporal relationship between exposure to the agent in question and the outcome of interest.[9]

It is upon consideration of this totality of factors that petitioners' experts based their opinions that, likelier than not, Bendectin causes human limb defects. Pet. Br. 6-7.

II. THE INADEQUACY OF THE EFFORTS TO LOCATE *FRYE* OR SOME OTHER "RELIABILITY" THRESHOLD IN RULE 702

Merrell makes a feeble attempt to defend *Frye*, which we refute in Part II-A, *infra*. Merrell then tries, as do its supporting *amici*, to locate some less stringent "reliability" threshold in Rule 702. The latter, even if correct, would require a reversal of the decision below. But it is not correct. As we show in Parts II-B and II-C, *infra*, these arguments attempt to secure by judicial fiat what both the Civil Rules Advisory Committee and the Solicitor General recently acknowledged is *not* now in the FRE. In Part II-D, *infra*, we furnish the analytical demonstration, from the text and structure of the FRE, of the infirmities of the attempt to locate a reliability threshold in Rule 702.

A. The "General Acceptance" Standard of *Frye*

Although Merrell clings at least nominally to a defense of the proposition that the FRE incorporates the "general acceptance" standard of *Frye*, that standard is condemned by a wide cross-section of *amici* as both a misreading of the FRE and bad policy. See p. 1, *supra*. Recently, the Civil Rules Advisory Committee made clear that it, too, believes *Frye* was not adopted by the

[9] Einarson, *et al.*, *supra*, at 822. The authors further cautioned that their methodology might have "masked" evidence of Bendectin's causative properties. *Id.* The Sixth Circuit decision that Merrell cites for the consistency of courts in its favor (Resp. Br. 5), after reviewing Merrell's "near-library" of data (Resp. Br. 11), actually found that Merrell "overstates the power of these statistical studies," which are "by no means conclusive" and show "possible" causation. *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1357 (6th Cir. 1992), *cert. denied*, 113 S. Ct. 84 (1992). The Sixth Circuit also noted that Merrell had been refused summary judgment in eight cases. *Id.* at 1352.

FRE and should not be added. Although proposing that the threshold for admission of expert testimony be raised to require greater reliability, the Committee emphasized that its proposal "does not mandate a return to the strictures of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) (requiring general acceptance of the scientific premises on which the testimony is based)." *Proposed Rules*, 137 F.R.D. 53, 157 (1991).

Merrell's lone effort to salvage the *Frye* test rests entirely on the proposition that because Congress did not expressly say it was abandoning *Frye*, the test's survival should be inferred. Resp. Br. 25-26. But a legislative intention *not* to accept the *Frye* rule is manifest in the enactment of the FRE: (1) *Frye* was widely condemned by commentators at the time the FRE were adopted (Pet. Br. 17); (2) as has been recognized by this Court (Pet. Br. 29), the Solicitor General (p. 7-8, *infra*), and recently the Civil Rules Advisory Committee (p. 6-7, *infra*), the framers expressly avowed an intent to remove common law barriers to the admissibility of expert opinion testimony; and (3) the plain words of Rule 402, read in conjunction with Rules 701-06, articulate a different standard than *Frye* (Pet. Br. 18-28).[10]

B. The Civil Rules Advisory Committee's Proposal

Merrell and many of the opposing *amici* urge this Court to find in the *present* text of Rule 702 the limitation on admissibility that the Civil Rules Advisory Committee proposed to *create* by amending Rule 702. In recently proposing to add a requirement that expert testimony be limited to "reasonably reliable" information, *Proposed Rules*, 137 F.R.D. 53, 73, 156 (1991), the Committee understood that this limitation did not already

[10] In any event, *Frye* had never been embraced by this Court, and, as of 1975, had never been applied by a federal appellate court to a civil case; indeed, only on three occasions, the first in 1984, has *Frye* been invoked to exclude expert testimony in a civil case. States' Br. 1-2 & n.1, 4-5. *Frye* has always been understood to be premised at least in part on considerations unique to criminal cases: the higher burden of proof, and the policy concern that criminal defendants could not afford to hire experts to counter those presented by the prosecutor. See *id.* 2-4. This, then, is hardly a situation where there was settled law for civil cases that Congress could be thought by silence to have incorporated into the FRE.

exist in Rule 702.

The Committee recognized that the greatly increased use of expert testimony following enactment of the FRE "was intended by the drafters of the rule, who were responding to concerns that the restraints previously imposed on expert testimony were artificial and an impediment to the illumination of technical issues in dispute." *Id.* at 156. But, the Committee opined, times have changed since 1975: now "large expenditures for marginally useful expert testimony ha[ve] become commonplace," and "excesses . . . should be curtailed." *Id.* at 156-57. The Committee explained that its "revision" (requiring that expert testimony be "reasonably reliable") would "limit the use, but increase the utility and reliability" of "testimony bearing on scientific and technical issues." *Id.* at 156; *see also id.* at 157.

Even this proposal, designedly less preclusive than *Frye*, proved to be highly controversial.[11] The proposal was formally withdrawn, to be resubmitted to a newly appointed Advisory Committee on evidence. This Court should not find *already in Rule 702* what the Civil Rules Advisory Committee correctly understood required amendment to achieve.

C. The Solicitor General's Proposal

In a brief filed on January 19, 1993, the Acting Solicitor General asked this Court to interpret Rule 702 as already containing some of the "reforms" that President Bush's Council on Competitiveness previously declared could be accomplished

[11] *See, e.g.*, Jack B. Weinstein, *Rule 702 of the Federal Rules of Evidence is Sound; It Should Not Be Amended*, 138 F.R.D. 631, 636 (1991); Advisory Committee on the Civil Rules, *Summary of Comments on 1991 Proposed Amendments*, May 20, 1992, at 62-66. Indeed, the Criminal Rules Advisory Committee strongly opposed the Civil Rules Advisory Committee's proposed amendment of Rule 702, reflecting significant "tensions and confusion" in the area of expert testimony. Edward R. Becker & Aviva Orenstein, *The Federal Rules of Evidence After Sixteen Years — The Effect of "Plain Meaning" Jurisprudence, the Need for an Advisory Committee on the Rules of Evidence, and Suggestions for Selective Revision of the Rules*, 60 Geo. Wash.L.Rev. 857, 861-62 & n.17 (1992). *See also* Minutes of the Advisory Committee on the Federal Rules of Criminal Procedure, April 23-24, 1992, at 13.

only through *amendment* of the FRE. A subcommittee of that Council, chaired by Solicitor General Starr, recommended "fifty specific *changes* to our *current* civil litigation system" which could be "implemented," *inter alia*, by "amendment to the rules of . . . evidence." *Proposed Civil Justice Reform Legislation*, 60 U. Cin. L. Rev. 977, 979 (1992) (emphasis added). Six of these changes related to the admissibility of expert testimony. *Id.* at 990.

The Starr subcommittee described the current state of evidence law, and its alleged defects, as follows:

> The Federal Rules of Evidence . . . eliminated many of the common law restrictions on the use of expert witnesses. . . .
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> . . . Currently, "expert" witnesses are permitted to offer testimony even if their theories are unproven and are not corroborated by other experts. The Council's recommendations would allow testimony based on respected minority or majority theories while excluding fringe theories.

Id. at 999.

According to the subcommittee's report, the "Action *Required*" to achieve these changes included amendments to Rule 702 that would "require expert testimony to be based on 'widely accepted' theories." *Id.* at 999. "It is contemplated that this requirement may be satisfied by expert testimony that is accepted by at least a substantial minority of experts in the relevant field." *Id.* at 1050. Yet the Acting Solicitor General's brief filed in this case asks the Court to find in the present text of Rule 702 what the Starr subcommittee earlier acknowledged necessitated amendment of that Rule. *See, e.g.*, U.S. Br. 19-20.

There is a raging contemporary debate about the desirability of changing the FRE to increase the foundational requirements for admitting expert testimony. See, e.g., p. 7, note 11, *supra*. However, as this Court observed in the context of another controversial provision of the FRE: "Our task in deciding this case . . . is not to fashion the rule we deem desirable but to identify the rule that Congress fashioned." *Green v. Bock Laundry Machine Co.*, 490 U.S. 504, 508 (1989).

D. Rule 702 Does Not Contain a Foundational "Reliability" Threshold

Under the interpretation we have proffered, the FRE as presently constituted impose several important restrictions on expert scientific testimony that a judge may invoke to exclude "junk science." Rule 201(g) empowers a judge to refuse admission to testimony in disproof of a fact that is amenable to judicial notice, *i.e.*, that is "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Rule 201(b).[12] The availability of this power disposes of many of the extreme hypotheticals proffered in opposing briefs. Rule 702 restricts expert testimony to subjects on which the fact-finder needs expert assistance, and requires that the expert who is to testify be qualified. Rule 703 — the provision expressly addressed to the foundation for expert testimony (entitled "Bases of Opinion Testimony by Experts") — requires that the hearsay "facts or data" upon which the expert's opinion is predicated be "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Rule 403 empowers the trial judge to exclude expert testimony on a case-specific, *ad hoc* basis when the probative value of the proffered testimony is substantially outweighed by, *inter alia*, "the danger of unfair prejudice, confusion of the issues, or misleading the jury."

Additionally, even if testimony survives these "gateways" and is admissible, the judge may counter perceived "venal experts" by calling a court-appointed expert (Rule 706), and the opposing party may through cross-examination and the testimony of its own expert witnesses inform the jury of the extent of scientific disagreement with the witness' position. Further, the judge possesses the customary powers to grant judgment as a matter of law, either before or after the jury's verdict, if "there is no

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[12] *See* Advisory Committee's Note to Rule 201(g). In the instant case, Merrell never suggested that the court could take judicial notice of the safety of Bendectin, and the district court, which recognized that it is possible on the existing record that Bendectin causes limb defects (J.A. 236), plainly would have rejected the suggestion had it been made.

legally sufficient evidentiary basis for a reasonable jury to have found for [a] party" (Fed. R. Civ. P. 50(a)(1)), or to order a new trial if convinced that the verdict is manifestly against the weight of the evidence (Fed. R. Civ. P. 59).[13]

In our opening brief we laid out this framework of existing tools permitting judicial scrutiny of testimony by experts. Pet. Br. 35-37. Merrell and its *amici*, however, ask this Court to discover still additional "foundational" hurdles to the admissibility of expert testimony in Rule 702 (the section which, conspicuously, *precedes* the section entitled "Bases of Opinion Testimony by Experts"). These hurdles are claimed to flow from the term "knowledge" (or "scientific . . . knowledge") and the reference to experts testifying "thereto." Resp. Br. 13-14.

The precise content these proponents would inject into Rule 702 varies widely, from the "'accepted standards' foundational requirement" urged by Merrell (Resp. Br. 27) to a multitude of variations proposed by *amici*. The very breadth of the proposals showered on this Court suggests that these inventive "interpretations" have no root in the statute's language or legislative history: there is no anchor to guide or constrain the inventors' imaginations, because there is nothing in Rule 702 addressed to foundation. The dissonance between these proposals and the actual text of Rule 702 is evident from a comparison of Merrell's formulation with the text of Rule 702. Merrell argues (Resp. Br. 26):

> In summary . . . Rule 702 of the Federal Rules of Evidence requires a determination not only (1) that the resolution of a question warrants the use of expert testimony and (2) that a particular expert is qualified in his or her field, but also (3) that the testimony proffered by an expert rests on a foundation reflecting the generally accepted standards in that field for validating expert assertions.

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[13] Moreover, the plaintiff must establish all the factual predicates without which the expert's views would be irrelevant. In this case, for example, petitioners must show that the mothers ingested Bendectin during the brief, critical period of limb formation in the fetus. Pet. Br. 7 n.20; J.A. 192.

But only standards (1) and (2) of Merrell's formulation can be found in the text of Rule 702:

> [1] If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, [2] a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise. (Brackets added.)[14]

Merrell's attempt to graft a third standard onto Rule 702 is new in this Court. Below, Merrell's position was that the expert testimony in this case was inadmissible because of Rule 703.[15]

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[14] Similarly, the Advisory Committee's Note explaining Rule 702 contains only the first two of Merrell's proposed standards, and also quotes a passage from Mason Ladd, *Expert Testimony*, 5 Vand. L. Rev. 414, 418 (1952), describing only the first two standards. Pet. Br. 31 n.58.

Merrell suggests that, as the Advisory Committee's Note to Rule 702 cited Wigmore's treatise for the proposition that evidence could be excluded if "unhelpful," the drafters meant to empower judges to keep out opinions that are not "reliable." Merrell distorts the meaning by taking the citation out of context. In the section of the treatise cited by the drafters (7 Wigmore § 1918), Wigmore was using "unhelpful" to describe expert testimony that was not needed, either because the jury could resolve the issue without the benefit of expert advice or because the testimony would be duplicative of other expert testimony proffering the same opinion. The Advisory Committee's Note invoked this passage of Wigmore to explain the drafters' use of the phrase "assist the trier of fact" in Rule 702. See Pet. Br. 30-33.

[15] The lone reference to Rule 702 in Merrell's brief below was the following introductory passage describing "the nature of the analysis required to determine whether expert testimony is admissible" (Ct. Appeals Br. 17):

> First, under Rule 702 of the FRE, a court must determine whether the admission of expert testimony will assist the trier of fact. Second, under Rule 703, a court must inquire into whether the expert testimony is based upon data of a type reasonably relied on by the experts in the field in forming opinions.

Id. The remainder of the brief invoked only Rule 703 and the district court's discretionary power under Rule 403. *Id.* 33, 35, 37, 42-43.

The decisions of the courts below never cited Rule 702; rather, the courts said they were following other circuits that had applied *Rule 703* to bar testimony by certain experts called by plaintiffs in Bendectin cases. J.A. 229, 240 n.1.[16] In opposing rehearing below, Merrell repeatedly declared that the court had properly decided on the basis of Rule 703.[17] Finally, in its brief in opposition to certiorari in this Court, Merrell defended the decision below as consistent with Rules 703 and 403, without argument based on Rule 702.[18]

What accounts for Merrell's sudden discovery that the term "knowledge" in Rule 702 is the locus of the relevant foundational requirement?[19] Obviously, Merrell now realizes that the foundational requirement expressly prescribed in Rule 703 does *not* authorize exclusion of the testimony of petitioners' witnesses, because that testimony is predicated entirely upon facts and data "of a type reasonably relied upon by experts in a particular field [teratology] in forming opinions or inferences upon the subject [whether a toxin causes birth defects]." Pet. Br. 5, 34-37.[20]

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[16] Merrell tells this Court (Resp. Br. 12 n.6) that the Ninth Circuit's citation in the opinion below of its prior decision in *United States v. Solomon*, 753 F.2d 1522 (9th Cir. 1985), signals that the decision below was predicated on Rule 702. That misreads *Solomon*. As a glance at *Solomon* reflects, the page of *Solomon* cited in the opinion below (p. 1526) adopted *Frye* apparently as a free-standing common law rule for scientific evidence; the prior page (p. 1525) — *not* cited by the Ninth Circuit below — described Rule 702 in a separate passage as a threshold test for all expert testimony.

[17] Opposition to Petition for Rehearing, filed Feb. 18, 1992, at 1, 5, 12, 13, 17.

[18] See Respondent's Brief in Opposition, at 9, 11, 14-15, 17, 19.

[19] We use the term "discovery" advisedly: we are aware of no antecedents either in the case law or the commentaries for finding a foundational requirement in Rule 702's words "knowledge" and "thereto," and none is cited in the opposing briefs. The belatedness of this discovery, supposedly made simultaneously by Merrell and several of its *amici*, attests to its lack of merit.

[20] Some *amicus* briefs attempt to justify exclusion on the basis of Rule 703, but the attempt is meritless. The data upon which petitioners' experts rely is the same data upon which Merrell's experts rely. The dispute that divides the experts is not over the appropriate facts and data to consult, but rather over the conclusions to be drawn therefrom.

The efforts to transform "knowledge" in Rule 702 into a foundational requirement fly in the teeth of the statutory language and structure. Rule 703's very title — "Bases of Opinion Testimony by Experts" — announces that *it* is the provision prescribing the foundational requirements.[21]

Reading Rule 702 to permit testimony only if based upon relatively well-settled propositions of "knowledge" not only displaces the function of Rule 703; it is incompatible with Rule 702's language explicitly allowing experts to testify "in the form of an opinion." Merrell asserts that Rule 702 does not permit an expert to offer "beliefs" (Resp. Br. 14), but a check of any dictionary will confirm that this word is a synonym for "opinions."[22]

The only reading of Rule 702 consistent with its wording is that which we have proposed: Where expert testimony would assist the trier of fact in resolving a factual issue, a qualified expert may utilize his or her specialized knowledge to proffer an opinion as to the issue, so long as the opinion is predicated upon facts or data meeting the foundational requirements of *Rule 703*.[23]

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[21] "Foundation" and "basis" are synonyms. BURTON'S LEGAL THESAURUS 234 (1980) ("foundation"); WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 182 (1981) ("basis"); BLACK'S LAW DICTIONARY 151 (6th ed. 1990) ("basis").

[22] *See, e.g.*, definitions of "opinion" in: WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1582 (1981); BALLENTINE'S LAW DICTIONARY 893 (3d ed. 1969). *See also* definition of "opinion evidence" in BLACK'S LAW DICTIONARY 1093 (6th ed. 1990).

[23] Merrell argues that Rules 702 and 703 cannot mean what they plainly say because that would result in a lower threshold for admitting expert opinion testimony than the thresholds expressly provided in the FRE for the taking of judicial notice (Rule 201) and the admission of learned texts (Rule 803(18)). Resp. Br. 16. But the distinction is obvious: a high threshold for use of judicial notice or admission of learned texts is required because these methods of proof are not available for cross-examination, and cross-examination was the principal bulwark against poor science

III. THE INADEQUACY OF THE EFFORT TO BRUSH OFF FEDERALISM CONSIDERATIONS

No party or *amicus* challenges petitioners' contentions that under California law the expert testimony in this case would be admissible and sufficient to sustain a verdict in favor of petitioners. As this evidence would be admissible in the courts of at least 45 and perhaps all 50 States (see p. 2, *supra*), it is inescapable, and Merrell concedes (Resp. Br. 27 n.18), that adoption of an interpretation of Rule 702 that required exclusion of this evidence would change the outcomes of cases arising under the substantive tort law of the States.

Merrell and its *amici* nonetheless dismiss this consequence as unimportant for three reasons: (1) petitioners' interpretation of the FRE, requiring admission of the testimony, would likewise be outcome determinative in States whose courts would not admit the testimony; (2) *Erie* is inapplicable if Congress has enacted rules that bar admissibility of the evidence; and (3) in any event, judge-jury allocations involve the "fundamental character" of the federal courts and thus are exempt from *Erie* concerns. All of these rejoinders are flawed.

1. State law determines the substantive tort standards and defines the evidence sufficient to establish a claim. If a State has set the plaintiff's burden so high that this evidence would not satisfy the burden — imagine, for example, a State that ruled, as the courts below did, that causation must be proved by statistically significant epidemiological evidence — the evidence might not even be relevant, and in any event would be insufficient to sustain the plaintiff's burden of going forward and would justify summary judgment. It is only the *exclusion* of evidence that threatens a State's primacy over its tort law, for

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envisioned by the drafters of the FRE. See Pet. Br. 17, 39-40. On this basis, Dean McCormick had argued prior to the drafting of the FRE that general acceptance was an appropriate threshold for judicial notice, but not for the admission of expert testimony. Pet. Br. 17. Furthermore, Merrell offers no explanation why, if the drafters wanted similar thresholds with respect to expert testimony, similar words do not appear in Rules 702 and/or 703.

only exclusion disables state substantive law from operating upon the entire body of information that the State deems relevant.

2. It is, of course, true that *Erie* does not apply *when* Congress enacts a valid statute that preempts state substantive law. But Merrell's argument here overlooks the weight that is owing to federalism concerns in determining *whether* Congress has enacted such a statute.

The crux of the controversy here is a question that is properly controlled by state tort law: whether causation sufficient to justify a compensatory award can be found on the basis of animal and chemical data, in conjunction with epidemiological data that may fall short of demonstrating causation at a 95 percent significance level. The District of Columbia Court of Appeals has said that it can. Pet. Br. 42. We contend, and no one has disputed, that California courts would hold likewise. The courts below, however, construed the Federal Rules of Evidence to dictate the opposite answer. In doing so, they mistakenly deferred to scientists on an issue that is properly one of tort law.

"Determining the legal consequences that flow from this imperfect state of knowledge lies beyond the domain of science." Carnegie Commission Br. 22. And the choice as to what quantum of probabilistic causation evidence will suffice to legitimate a compensatory award in a products liability case requires a policy choice balancing, *inter alia*, the injured party's interest in compensation against the defendant's interest in not being held liable without adequate justification.

The courts below failed to appreciate that the question of whether causation "is likelier than not" is a different question from the one pursued by pure science. As evidence scholar Charles Nesson, one of Merrell's counsel, has written:

> The legal standard requires neither *absolute* certainty nor the exacting level of certainty that scientists employ for the demonstration of scientific propositions. There is a difference, then, between the testifying expert and the lab scientist. An imaginative scientist exploring the hypothesis that a given toxic agent causes cancer is very likely to suspend scientific judgment on the ultimate

> question of causation until more testing or study can be done to eliminate alternative hypotheses. A doctor or lawyer or judge, on the other hand, often does not have the luxury of postponing a decision. Often he must make a judgment once he reaches a reasonable working conclusion. Likewise, we ask juries to come to conclusions without insisting on or waiting for scientific demonstration. The legal standard of proof would seem to require only a rational basis for the expert's opinion — a standard far short of scientific demonstration.

Charles Nesson, *Agent Orange Meets the Blue Bus: Factfinding at the Frontier of Knowledge*, 66 B.U. L. Rev. 521, 529-30 (1986) (emphasis added).

The "lab scientist's" standard of proof — statistical significance — is heavily weighted *against* finding causation. Pet. Br. 9-10. In consequence, as Nesson explains, imposing that standard as the threshold for finding causation in toxic tort cases "*is tantamount to institutionalizing an objectively determinable probability greater than .5 for cases in which proof of causation involves a disputed supposition about the working of nature.*" *Id.* at 538-39 (emphasis added). This point has been made widely in the literature, by both legal scholars and scientists.[24]

Of course, a State might opt for a substantive rule of law withholding compensation in the absence of "statistically significant" evidence, despite the tilt in favor of producers that Nesson warns "insulates companies from the consequences of negligently exposing persons to toxins" and creates disincentives

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[24] *See, e.g.*, Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of* Agent Orange *and Bendectin Litigation*, 86 Nw. U. L. Rev. 643, 667-68, 682-94, 697 (1992); V. Brannigan, V. Bier, and C. Berg, *Risk, Statistical Inference, and the Law of Evidence: The Use of Epidemiological Data in Toxic Tort Cases*, 12 Risk Analysis 343 (1992); D.H. Kaye, *Is Proof of Statistical Significance Relevant?*, 61 Wash. L. Rev. 1333 (1986); Steve Gold, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence*, 96 Yale L.J. 376 (1986); Neil B. Cohen, *Confidence and Probability: Burdens of Persuasion in a World of Imperfect Knowledge*, 60 N.Y.U. L. Rev. 385, 413-14 (1985).

for taking appropriate care.[25] But as the Carnegie Commission's brief explains (at 24), whether to do so is a function of "the social policies underlying products liability law."[26]

Several of the *amici* supporting Merrell explicitly ask this Court to weigh and resolve that policy choice in arriving at its interpretation of the FRE. The brief filed by the Acting Solicitor General asks this Court to hold that expert testimony not buttressed by statistically significant epidemiological results is not admissible because it is "insufficient *as a matter of law* to support a finding that Bendectin caused the birth defects at issue in this case." U.S. Br. 14 (emphasis added). Three *amici* predicate their arguments for a statistical significance threshold for admissibility on the proposition that a reduction in the number of tort recoveries will assure the supply of products and services and strengthen the insurance mechanism.[27]

These are considerations that (if true) are appropriate for consideration by the governmental entity responsible for developing substantive tort policy, to be weighed together with the other interests (such as compensating injured persons and deterrence) that are relevant to that policy. But surely Congress did not purport to be making tort policy when it enacted the

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[25] Nesson, *supra*, 66 B.U. L. Rev. at 537.

[26] For like reasons, it is a question of tort law, rather than evidence law, whether a State will require evidence suggesting a doubling of incidence of injuries before finding causation in the case of individuals. *Cf.* Resp. Br. 40. There is a developing trend in favor of awarding proportionate recoveries on the basis of evidence of an increase in incidence, even if less than a doubling. The recent report of the American Law Institute, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY, Vol. II, 369-75 (1991), strongly endorses proportionate awards, concluding that they better serve both the deterrent and the compensation goals of tort law. *See also* STEVEN SHAVELL, ECONOMIC ANALYSIS OF ACCIDENT LAW 115-17 (1987). The seminal decisions adopting proportionate awards are *Herskovits v. Group Health*, 664 P.2d 474 (Wash. 1983), and *McKellips v. Saint Francis Hospital*, 741 P.2d 467 (Okla. 1987).

[27] AMA Br. 18-26; Pharmaceutical Manufacturers' Association Br. 12-18; American Insurance Association Br. 24-28.

FRE; it went out of its way to avoid doing so. Pet. Br. 41-42. The FRE cannot plausibly be construed to erect a burden of proof for tort causation in excess of the traditional "more probable than not" standard for a civil case, or to preclude the consideration of expert testimony on the ground that, "as a matter of law," animal studies, chemical studies, and epidemiological studies lacking *95 percent* confidence — which regulatory agencies act upon every day — are inadmissible to prove causation.[28]

3. The foregoing analysis cannot be escaped by simply labeling the issue here — as Merrell does in passing — as one of mere allocation of fact finding between judge and jury. See Resp. Br. 27 n.18 (citing *Byrd v. Blue Ridge Rural Elec. Corp., Inc.*, 356 U.S. 525 (1958)). The interpretation of the FRE sought by Merrell does not merely allocate the responsibility for "truth-determining." Washington Legal Foundation Br. 5. Rather, the question here — whether the testimony is sufficient to prove causation — is an issue respecting the nature of the burden of proof, which this Court unequivocally has determined to be "substantive." *Dick v. New York Life Ins. Co.*, 359 U.S. 437, 446 (1959).

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[28] Merrell and others argue that what regulators do is different, because regulators only need evidence of "risk" to act, while courts require a rigorous showing of "actual causation" before awarding tort damages. Resp. Br. 39-40. This is a false dichotomy. Banning products from the market imposes heavy social costs, just as awarding compensation does. In each case, the government does not want to take that step unless there is a sufficient showing of probability of "actual causation." Thus, in each case, government expects scientists to employ the methodologies most appropriate to making that assessment.

To be sure, the precise confidence level required of the probabilistic evidence before deciding to act may differ, depending upon the governmental action that is contemplated and the content of government policy, but that difference might cut either way. In some instances, government opts to allow products on the market, and relies on the tort system as a safety net, both to compensate those who are injured and to discover new information (through the continuous accumulation of information from individual cases) that may dictate the need for renewed regulatory interest. In these instances, government requires a *greater* showing of probability of causation before regulating than before compensating.

IV. THE PROPER DISPOSITION OF THIS CASE

Unless this Court affirms both holdings of the Ninth Circuit challenged here — that the FRE requires general acceptance as a threshold to the admissibility of expert testimony, and that (contrary to federal regulations and many *amici* scientists) "reanalysis" of epidemiological data is a "technique" subject to the *Frye* rule and is not generally accepted unless first published and peer reviewed — the normal course would be to reverse and remand for further proceedings. The briefs of Merrell and some *amici* raise two alternatives, however, that necessitate brief discussion.

1. Merrell and others ask this Court, if it rejects the Ninth Circuit's interpretation of the FRE, to determine in the first instance whether the evidence is admissible under the proper standard. We have no objection to that course. The testimony of petitioners' experts, from the ultimate conclusions stated in affidavits reprinted in the Joint Appendix to the hundreds of pages of testimony in which each expert carefully recounts the precise facts, data, methodology and reasoning upon which these conclusions are predicated,[29] measured against the pertinent tort law of California, demonstrates that the evidence here is admissible under any of the standards proffered in any of the briefs supporting Merrell (except those demanding prior publication and peer review as a precondition to admissibility). Indeed, as the Ninth Circuit's opinion reflects, the testimony would have been admissible even under its erroneous interpretation of the FRE, but for that Court's factual error respecting the functions of publication and peer review. *See* Pet. Br. 47-49; Chubin Br. *passim*.

2. The American Law Professors' brief broaches the option of this Court's dismissing this case to await the possible promulgation of a new rule by the recently appointed Advisory Committee on evidence, but then concludes that the Court should *not* dismiss. Law Profs. Br. 28-29. We agree, and briefly highlight certain factors that support the Court's deciding the issue now.

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[29] Tabs 12, 21, 26, 32, cited in Pet. Br. 3 n.4.

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In the Supreme Court of the United States

OCTOBER TERM, 1992

WILLIAM DAUBERT AND JOYCE DAUBERT, ET AL.,
PETITIONERS

v.

MERRELL DOW PHARMACEUTICALS, INC.

ON WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENT

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QUESTION PRESENTED

Whether evidence of causation proffered by petitioners failed to meet the requirements of the Federal Rules of Evidence concerning the admissibility of expert scientific testimony.

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In the Supreme Court of the United States

OCTOBER TERM, 1992

No. 92-102

WILLIAM DAUBERT AND JOYCE DAUBERT, ET AL., PETITIONERS

v.

MERRELL DOW PHARMACEUTICALS, INC.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENT

INTEREST OF THE UNITED STATES

The United States is vitally interested in the issue of the admissibility of expert testimony concerning scientific theories in federal court. The federal government is a party to a far greater number of civil cases "on a nationwide basis than even the most litigious private entity." *United States* v. *Mendoza*, 464 U.S. 154, 159 (1984). In addition, the government is solely responsible for the enforcement of federal criminal laws. Because of the great diversity of its civil and criminal litigation, the federal government finds itself supporting the admission of scientific theories in some cases while opposing their admission in others. The federal government is therefore interested in a principled approach to resolution of the question presented in this case.

STATEMENT

1. This case involves the admissibility of expert opinion testimony concerning epidemiology. Epidemiology, the study of disease distribution in human populations, is directed to determining factors that are likely to cause disease. To the extent pertinent here, epidemiologists use statistical methods for two distinct purposes. First, they use them to uncover statistical *associations* between risk factors and the incidence of disease. Second, because the mere existence of a statistical association between two variables does not mean that one *caused* the other, the researcher can attempt to draw conclusions about causation based on the strength of the relationship and other factors. See generally M. Dore, *A Commentary On The Use Of Epidemiological Evidence In Demonstrating Cause-In-Fact*, 7 Harv. Envtl. L. Rev. 429, 431-433 (1983); see also *In re Agent Orange Product Liability Litigation*, 611 F. Supp. 1223, 1231 (E.D.N.Y. 1985) (Weinstein, J.), aff'd, 818 F.2d 187 (2d Cir. 1987). Because the statistical concepts used in such studies are helpful to an understanding of the record in this case, we review them briefly here.

Researchers conducting epidemiological studies will ordinarily begin by identifying a group of persons and determining if those persons have been exposed to the suspect factor (in this case, Bendectin). Researchers will then determine the extent to which the disease outcome occurs in the each of the two subsets—the exposed and the non-exposed groups—of the population being examined. This type of analysis will provide the rates of incidence (number of cases within that defined population) for the exposed and non-exposed persons. Using those figures, a researcher can calculate the "Relative Risk" statistic. Relative Risk is a ratio of the incidence rate among those exposed in comparison to the incidence rate among those not exposed to the suspect factor. Thus, when a Relative Risk equals 1.00 there is no difference between the rates of disease occurring between the exposed group and the non-exposed group. A Relative Risk

figure greater than 1.00 (*e.g.*, 1.30) indicates that the incidence of a disease is higher among the group of persons exposed to the suspect factor than among the group that was not exposed. Conversely, a Relative Risk of less than 1.00 (*e.g.*, 0.90) indicates that the incidence of a particular disease is lower among the persons exposed to the suspect factor, when compared with those not exposed. See *Turpin* v. *Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1353 n.1 (6th Cir.), cert. denied, 113 S. Ct. 84 (1992); *DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 947 (3d Cir. 1990); *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 311-312, modified, 884 F.2d 166 (5th Cir. 1989), cert. denied, 494 U.S. 1046 (1990).

Once a Relative Risk figure is obtained, the epidemiologist must determine the likelihood that the figure could have arisen due to chance alone. That determination is necessary because, owing entirely to chance, a disease will not typically occur at *precisely* the same rate among any two groups of healthy people.[1] The procedure by which the effects of chance are excluded involves the application of basic statistical principles with which this Court is familiar. See, *e.g.*, *Hazelwood School District* v. *United States*, 433 U.S. 299, 308-312 (1977); *Castaneda* v. *Partida*, 430 U.S. 482, 495-499 & nn.16-18 (1977). The

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[1] Thus, it is impossible to say from the mere fact that the Relative Risk statistic is somewhat above or below 1.0 whether there is any real relationship between the suspect factor and the disease. The situation is analogous to obtaining more of one number than another when a die is rolled a dozen times—that may well be the result of random chance, rather than the die being "loaded." The principle is also exemplified by another quintessential example of the operation of chance—the tossing of a fair coin. While the chance that the coin will turn up heads is always 50 percent for each throw, the number of heads that results from numerous throws will not necessarily be equal to half the total number of throws. For a small number of throws the departure from the expected value (*i.e.*, half), may be quite large relative to the total number of throws. See D. Freedman, R. Pisani, R. Purves & A. Adhikari, *Statistics* 248 (2d ed. 1991).

fundamental point is both simple and intuitive. In any purely random drawing "the results * * * are likely to fall in the vicinity of the expected value." *Castaneda* v. *Partida*, 430 U.S. at 496 n.17. In fact, the distribution of the results of such a random drawing around the expected value can be predicted by statistical principles. Approximately 68 percent of the results will cluster within one standard deviation of the expected value, while approximately 95 percent will cluster within two standard deviations. See D. Freedman, R. Pisani, R. Purves & A. Adhikari, *Statistics* 63-82 (2d ed. 1991). If an observer is trying to determine whether an outcome (such as the results of tossing a coin or casting a die) is consistent with the operation of chance, or whether something else may be at work (for example, the coin may not be "fair" or the die may be "loaded"), he should be unwilling to rule out chance unless the distribution resulting from the experiment differs sufficiently from the distribution predicted by chance. See, *e.g.*, *Castaneda* v. *Partida*, 430 U.S. at 497 n.17 ("As a general rule for such large samples, if the difference between the expected value and the observed number is greater than two or three standard deviations, then the hypothesis that the jury drawing was random would be suspect to a social scientist."); *id.* at 494 n.13.

These principles of probability can be adapted to the context of drawing samples from a population and arriving at conclusions about that large population based on what is learned from the sample. An epidemiologist wants to compare the incidence of fetal malformation in the exposed and non-exposed groups. The problem might be analogized roughly to an experiment designed to learn whether a pair of dice are "loaded" by comparing the distribution of the outcomes they produce to the distribution of the outcomes produced by a second pair of dice, which we know to be exquisitely balanced. A practical problem in designing the epidemiological experiment is that the actual populations of exposed and non-exposed persons are too large and too indeterminable to be compared directly with one another. Because it is impractical to study *every* member of the exposed and the non-exposed groups, learning the incidence of malformation in each of the two groups necessarily involves "sampling."

A characteristic of sampling is that the incidence of a quality in the sampled group is not necessarily *identical* to the incidence of that characteristic in the general population. See *DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d at 946. But the result is likely to be "in the vicinity," *Castaneda* v. *Partida*, 430 U.S. at 496 n.17, of the number produced by the sampling technique. Thus, if sampling should show that four mothers out of one thousand in the non-exposed group gave birth to deformed children, while six exposed mothers out of one thousand from the exposed group did so, the researcher cannot assume that each of these figures necessarily represents the actual incidence of fetal malformation in the two groups sampled. But he can estimate that the true value for each group is somewhere "in the vicinity" of that shown by the sample. To calculate *how close* the real population percentage is likely to be to the figure observed in the sample, statisticians use "confidence intervals."

A confidence interval is a way of graphically representing the probability that a sampling result was due to something other than chance. The range of possible "true" values clusters around the figure obtained by sampling. By choosing a sufficiently wide interval of values around the figure obtained by sampling, the researcher can be reasonably confident that the true population incidence will be captured in that interval. For example, since there is a 95 percent chance that the "true" value lies within two standard deviations of the sample figure, that particular "confidence interval" (*i.e.*, two standard deviations) is therefore said to have a "confidence level" of about 95 percent.[2] It is important to

[2] A random sampling from the population would technically be measured by its "standard error" rather than by its "standard

recognize that the real population standard in which the researcher is interested—*e.g.*, what percentage of Bendectin users and nonusers in the actual population gave birth to children with limb malformations—is unchanging. While it is customary (and, in many cases, easier) to speak of "a 95 percent chance" that the actual population percentage is within two standard deviations of the figure obtained from the sample, "the chances are in the sampling procedure, not in the parameter." D. Freedman, R. Pisani, R. Purves & A. Adhikari, *supra*, at 351; *id.* at 397. What the short-hand expression actually means is that if the sampling from the general population were repeated numerous times, the "real" population figure would be within the confidence interval 95 percent of the time. *Id.* at 351. The "real" figure would be outside that interval the remaining five percent of the time.

Having obtained a sample figure for each of the exposed and non-exposed populations, the researcher may compute the Relative Risk statistic by dividing the former by the latter. Evaluating the meaning of the figure obtained entails recognition that both the numerator and the denominator will often be mere approximations of the real world data. The fact that the Relative Risk statistic differs from the "normal" value of 1.0 will therefore often reflect nothing more than the chance variability inherent in each of the two sampling procedures. Specifically, if the expected "normal" value of 1.0 is within the 95 percent confidence interval of the Relative Risk statistic obtained in the study, the result of the study is close enough to the normal value as to be expected simply from chance in a large number of cases. If the 95 percent confidence interval does *not* include the expected value for the Relative Risk statistic, a statistically significant *association* has been identified.

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deviation." For present purposes, the difference in terminology is not significant because the distribution of the outcomes is the same as for other random drawings.

A statistically significant *association* does not by itself tell the researcher anything definitive about *causation* even as a general matter, much less in the case of a particular tort plaintiff. "Because we often may not understand the mechanisms by which a drug causes human injury, epidemiological correlation alone does not constitute proof of causation." J. Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L.J. 301, 329 (1992); Dore, *supra*, 7 Harv. Envtl. L. Rev. at 431; accord K. Hall & E. Sibergeld, *Reappraising Epidemiology: A Response To Mr. Dore*, 7 Harv. Envtl. L. Rev. 441, 445 (1983). Thus, even after finding a statistically significant association, researchers must turn to other factors to draw inferences about causation, including a study of the temporal relationships involved (*i.e.*, cause must precede effect), the strength of the correlation (*e.g.*, the higher the strength of the association the less likely it is that other factors are involved), the coherence of the evidence (*e.g.*, taking higher doses of a drug should increase likelihood of observable effects), and the consistency on replication (*i.e.*, multiple replications diminish the probability that results are spurious or the product of methodological flaws). See Sanders, *supra*, 43 Hastings L.J. at 329-330. It is from that combination of analyses that experts then attempt to draw conclusions about the likelihood of causation.

2. Petitioners William and Joyce Daubert brought this products liability action, individually and as Guardians Ad Litem for their infant son, Jason Daubert, against Respondent Merrell Dow Pharmaceuticals, Inc. (Merrell Dow) in the Superior Court for San Diego County, California. Petitioner Anita De Young also sued Merrell Dow in the same court, individually and as Guardian Ad Litem for Eric Schuller. Petitioners all alleged that Bendectin, a prescription anti-nausea drug formerly manufactured by Merrell Dow for pregnant women, caused the limb reduction birth defects from which Jason Daubert and Eric Schuller suffer. Merrell Dow removed both cases to

the United States District Court for the Southern District of California, where they were consolidated.

Following discovery, Merrell Dow moved for summary judgment on the issue of causation. relying, *inter alia*, on the affidavit of Dr. Stephen H. Lamm, a physician and epidemiologist. After reviewing all published epidemiological studies concerning Bendectin and birth defects (over 30 published studies involving more than 130,000 patients), Dr. Lamm concluded that there was no statistically significant association between Bendectin and birth defects in general, or limb reduction birth defects in particular. Pet. App. A2. Petitioners opposed summary judgment, proffering the contrary opinions of eight experts. Those experts based their opinions on: (1) *in vitro* (test tube) and *in vivo* (animal teratology) tests, chemical structure analyses; and (2) in three instances (Drs. Gross, Swan, and Glasser), "reanalysis" of data from the published epidemiological studies relied on by Merrell Dow. *Id.* at A9, A11-A13.

The district court granted Merrell Dow's motion for summary judgment. Pet. App. A6-A15. Because Merrell Dow was the movant, the district court viewed "the evidence in a light most favorable to [petitioners]" to determine "whether a fair-minded jury could return a verdict for the [petitioners] [based] on the evidence presented." *Id.* at A7, quoting *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 251-252 (1986). But because petitioners bore the ultimate burden of proof on the issue of causation at trial, the district court held that the evidence favoring petitioners had to raise a material question as to whether Merrell Dow's conduct "was more probably than not the proximate cause of the accident." Pet. App. A7-A8.

Assessing the evidence under those standards, the district court found it insufficient to withstand summary judgment. Pet. App. A13-A15. The *in vitro* and *in vivo* tests and the chemical structure analyses were insufficient by themselves absent epidemiological studies—*i.e.*,

studies showing a link between Bendectin and fetal malformations in human beings, rather than merely test-tube chemical reactions or animal reactions to highly-concentrated amounts of a chemical. *Id.* at A9 ("causation may be shown only through reliance upon epidemiological evidence"); see also *id.* at A13-A14. Thus, the animal and chemical studies "lack[ed] the sufficient foundation necessary under [Fed. R. Evid.] 703" for admission into evidence and were "insufficient to take the issue [of causation] to the jury." *Ibid.*

The district court also found insufficient the "reanalysis" of epidemiological data by Drs. Gross, Swan, and Glasser. Pet. App. A14-A15. First, the district court rejected Dr. Gross's "study" because, *inter alia*, "nowhere [did] it state that Bendectin sales increased the relative risk of limb reduction defects to a level significantly above 1.0 with a confidence interval that did not include unity," *id.* at A15—*i.e.*, in statistical terms, Dr. Gross's work, even if admissible, showed no statistically significant relationship between Bendectin and fetal malformation. Second, the district court found Dr. Swan's "unsupported allegations" of a "statistically significant" connection between Bendectin and limb defects "similarly insufficient." Finally, the court adverted to the Fifth Circuit's *Brock* opinion, in which that Court noted that Dr. Glasser, while finding a "relative risk of 1.49" for Bendectin in his study, "admit[ted] that the confidence interval was from 0.17 to 3 * * * render[ing] the study statistically insignificant." *Id.* at A14-A15, citing *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d at 312-313. "[T]he strongest inference to be drawn for [petitioners]," the district court concluded, "is that Bendectin could possibly have caused [their] injuries," a claim insufficient to take this matter to the jury. *Ibid.*

3. The court of appeals affirmed. Pet. App. A1-A5. Stating that "[e]xpert opinion based on a scientific technique 'is admissible if it is generally accepted as a reliable

technique among the scientific community.'" *Id.* at A2, citing, *inter alia*, *Frye* v. *United States*, 293 F. 1013, 1014 (D.C. Cir. 1923), the court of appeals held that petitioners could not establish causation "in the absence of critically analyzed epidemiological studies establishing a connection between the use of the drug and the birth defects." Pet. App. A3. The court agreed with the district court that petitioners had failed to present such evidence. The "animal and chemical studies were insufficient" because of the "need to verify such data with epidemiological evidence." *Ibid.* The "reanalyses" of the epidemiological data were also insufficient because the studies "were unpublished, not subjected to the normal peer review process and generated solely for use in litigation." *Id.* at A5. Because petitioners' offerings "provide insufficient foundation to allow admission of expert testimony to the effect that Bendectin caused [petitioners'] injuries," petitioners "could not satisfy their burden of proving causation at trial" and, thus, summary judgment was appropriately entered against them. *Ibid.*

SUMMARY OF ARGUMENT

The Federal Rules of Evidence provide ample authority for a federal court to "screen" expert opinion testimony and to exclude such evidence if it is insufficiently reliable, or if it would unfairly mislead or confuse the jury. The district court properly exercised that authority in this case. While the court of appeals' reasoning was considerably broader than necessary to resolve this case—insofar as it relied on the restrictive *Frye* rule as the exclusive test for the admissibility of expert scientific testimony—its judgment affirming the district court was correct.

1. Rules 702 and 703, in conjunction with Rule 403, set forth the standards governing the admissibility of scientific expert opinion in federal court. Rule 702 provides that, in addition to demonstrating that he has rele-

vant training or experience, a witness proffered as an expert must testify to "scientific, technical or other specialized *knowledge*" that will "*assist*" the trier of fact to discharge its duties in the instant case. Petitioners' submission that the trial court lacks authority to exclude evidence it finds unreliable disregards the Rule's command that a witness must testify to "knowledge" that will "assist" the trier of fact, not to unsubstantiated hypotheses or theories. In light of Rule 702's broad purpose of assisting the jury, we read the requirement of knowledge broadly as embodying not only irrefutable certitudes but also facts that can be established with a sufficient level of reliability to be helpful to the jury's determinations of the issues in a particular case. The rule of *Frye* v. *United States*, 293 F. 1013 (D.C. Cir. 1923), which requires "general acceptance" of a principle before evidence based on it may be admitted, has some usefulness in fulfilling that purpose—a trial judge cannot err by *admitting* testimony that is based on the unexceptionable application of universally accepted principles. We believe, however, that the *Frye* rule is too limiting to serve as a rule of exclusion in all circumstances. Thus, while we agree that Rule 702 requires a careful examination of the reliability of expert scientific evidence in light of the purpose for which it is offered (as all courts of appeals that have considered the question have concluded), we also agree with the minority view that the inquiry should be guided by a broader range of factors than those suggested by the strict *Frye* formulation.

In the ordinary case, the factors informing whether an expert's testimony is sufficiently reliable to be of assistance will include: (1) whether the technique relied on by the expert has achieved acceptance by at least a significant minority within the field; (2) whether the potential rate or possibility of error can be estimated (and the extent to which any uncertainty on this score would tend to favor the opponent of the evidence); (3) the degree to which subjectivity in the analysis renders

intelligent evaluation of the expert's conclusions impractical, requiring the trier to take the conclusions "on faith"; and (4) the extent to which the expert has exposed his methodology or conclusions to peers through publication or otherwise. The first factor will often be dispositive in cases where a methodology has been tested for a significant period of time, since a known technique which has been able to attract at most minimal support from those most likely to possess the ability to identify its flaws can be presumed to be unreliable. The court may admit expert testimony that relies on a scientific technique that is so novel that it has not yet been widely examined by those best qualified to identify its failings, but only in circumstances that assure its reliability in light of the purpose for which it is offered. When, as here, the technique relies on statistical analysis, its proponent must carry the burden of showing not only an objectively ascertainable margin of error, but also that the margin of error is significantly lower than what ordinarily would be expected from the operation of chance alone.

2. Our view that Rule 702 incorporates a "reliability" requirement is supported not only by the plain language of that Rule, but also by the related requirements of Rule 703. Rule 703 authorizes experts to testify to conclusions or inferences based on "facts or data" not admissible in evidence, but only if such "facts or data" are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." The Advisory Committee notes make clear that a district judge applying that rule should concentrate "on the validity of the techniques employed" by such a "hearsay" expert. We believe it implausible to suggest that the Rules of Evidence were intended to require courts to examine the validity of scientific techniques *only* when those techniques are used by such "hearsay" experts, leaving other expert witnesses completely free to give testimony based on unfounded theories. It is far more

sensible to view Rule 703 simply as extending to the testimony of hearsay experts the same requirements of trustworthiness that the drafters expected would be applied to expert testimony generally.

3. Evidence that satisfies the admissibility standards of Rules 702 and 703 may nonetheless be excluded under Rule 403, which vests the trial judge with discretion to prevent the jury from misusing otherwise admissible relevant evidence. Thus, expert testimony that may otherwise be sufficiently reliable for a limited purpose can be excluded when it is likely to confuse or mislead the jury about related issues for which it is not sufficiently reliable to be independently admissible, or when it has an undue tendency to suggest decision on an unsubstantiated, rather than a rational, basis.

4. There is no support in the Federal Rules of Evidence for petitioners' overriding thesis that the rules evince a plan to leave entirely to the jury the task of assessing the reliability of expert testimony, without any preliminary "screening" function for the court. The Rules themselves clearly provide that all questions concerning the admissibility of evidence must "be determined by the court." Fed. R. Evid. 104(a). This Court has made clear that this broad authority encompasses the responsibility to decide conclusively preliminary questions of fact on which the admissibility of evidence depends. See *Bourjaily* v. *United States*, 483 U.S. 171 (1987). Whether evidence is sufficiently reliable to qualify as "knowledge" under Rule 702, no less than whether the factual predicate for admissibility under a hearsay exception has been shown, is just such a preliminary question that the rules reserve for the trial judge.

5. Assessed under the foregoing principles, the court of appeals' conclusion that the testimony of petitioners' experts was too unreliable to be admissible under the federal rules was correct. Petitioners' "reanalysis" of published epidemiological studies produced statistically insignificant results—*i.e.*, to the extent their findings for

the exposed population departed from the corresponding "expected" values, the degree of departure was consistent with what a researcher would expect based solely on the chance variability of the sampling procedure. Because scientific norms generally require that results be statistically significant to be considered reliable, petitioners bore a heavy burden to demonstrate that the proffered testimony was probative even without satisfying those norms. Petitioners failed to meet that burden. Their epidemiological evidence accordingly had no probative value in demonstrating even a general *association* between Bendectin and fetal malformation, much less that that drug more probably than not was the *cause* of petitioners' injuries. Without reliable epidemiological data, petitioners' remaining evidence (consisting of various *in vitro* and *in vivo* animal tests, together with chemical structure analyses), was insufficient as a matter of law to support a finding that Bendectin caused the birth defects at issue in this case. In these circumstances, summary judgment was appropriately entered against petitioners, and the decision below should be affirmed.

ARGUMENT

THE COURTS BELOW PROPERLY EXCLUDED THE EVIDENCE OF CAUSATION PROFFERED BY PETITIONERS AND CORRECTLY ENTERED JUDGMENT AGAINST THEM

This case concerns the correct standard for determining the admissibility of expert scientific testimony. The majority of the courts of appeals hold that the admissibility of such evidence is governed by the test first articulated in *Frye* v. *United States*, 293 F. 1013 (D.C. Cir. 1923).[3] *Frye* held that expert testimony based on a

[3] See, *e.g.*, *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128 (9th Cir. 1991) (opinion below); *Christophersen* v. *Allied-Signal Corp.*, 939 F.2d 1106, 1110-1111, 1115-1116 (5th Cir. 1991) (en banc), cert. denied, 112 S. Ct. 1280 (1992); *United States* v. *Smith*, 869 F.2d 348, 351 (7th Cir. 1989); *United States* v. *Shorter*, 809 F.2d 54, 59-60 (D.C. Cir.), cert. denied, 484 U.S. 817 (1987); *United States* v. *Metzger*, 778 F.2d 1195, 1203 (6th Cir. 1985), cert. denied, 477 U.S. 906 (1986); *United States* v. *Smith*, 776 F.2d 892, 898 (10th Cir. 1985); *United States* v. *Alexander*, 526 F.2d 161, 163-164 (8th Cir. 1975).

scientific technique is admissible only if there has been a preliminary showing that the technique has gained general aceptance in the particular field in which it belongs. See *Frye* v. *United States*, 293 F. at 1014. The Second, Third, Fourth, and Eleventh Circuits, on the other hand, have rejected the holding of *Frye* in favor of a more generalized inquiry into the relevance and reliability of the expert evidence. In those four circuits, the trial judge may nonetheless exclude scientific evidence that he finds insufficiently reliable to aid the jury in resolving the issues in the case.[4]

Petitioners endorse the minority view insofar as it rejects the holding of *Frye*. Petitioners reject, however, any suggestion that a federal trial court may exclude otherwise relevant expert testimony based on its own preliminary conclusion that the methodology employed by the witness is not sufficiently reliable to be of assistance to the jury. Petitioners therefore disagree with the unanimous conclusion of the courts of appeals that *some* independent preliminary inquiry into the reliability of a scientific technique—whether under *Frye* or a more relaxed standard—is required by the federal rules. In petitioners' view, once a witness is shown to have some training in an area generally pertinent to the subject matter of the litigation, the jury alone must be entrusted with the determination whether the witness's methodology and

[4] See, *e.g.*, *United States* v. *Jakobetz*, 955 F.2d 786, 793-797 (2d Cir.), cert. denied, 113 S. Ct. 104 (1992); *United States* v. *Piccinonna*, 885 F.2d 1529, 1536-1537 (11th Cir. 1989); *United States* v. *Downing*, 753 F.2d 1224, 1237-1240 (3d Cir. 1985); *United States* v. *Baller*, 519 F.2d 463, 465-466 (4th Cir.), cert. denied, 423 U.S. 1019 (1975).

conclusions are reliable. Pet. Br. 15, 32-33, 39-40. We disagree. For the reasons that follow, the Federal Rules of Evidence require trial courts to determine independently, as a preliminary matter, whether a scientific process or method is sufficiently reliable to be helpful in determining a fact in issue.

A. Under The Rules Of Evidence, An Expert Witness May Testify Only To "Knowledge" That Is Sufficiently Reliable To Assist The Trier Of Fact

1. Rules 702 and 703, together with Rule 403, provide the framework for the admissibility of expert testimony. The starting place for our discussion is Rule 702. Because the Federal Rules of Evidence are a legislative enactment, we must "turn to the 'traditional tools of statutory construction' in order to construe their provisions." *Beech Aircraft Corp.* v. *Rainey*, 488 U.S. 153, 163 (1988) (citations omitted). Our analysis therefore begins with the language of Rule 702. *Ibid.*; see also *Huddleston* v. *United States*, 485 U.S. 681, 687 (1988). That language is clear. In addition to a showing that the witness has relevant training or experience, an individual proffered as an expert must testify to "scientific, technical or other specialized *knowledge*" that will "*assist*" the jury to discharge its duties in the instant case.

The principal flaw in petitioners' analysis of Rule 702 is that it ignores the requirement that the subject of the witness's testimony be helpful "knowledge." The rule does not define that term and, accordingly, absent some clear indication to the contrary, it must be given its ordinary meaning. *Chapman* v. *United States*, 111 S. Ct. 1919, 1925-1926 (1991); *Russello* v. *United States*, 464 U.S. 16, 21 (1983). In ordinary parlance, "knowledge" refers to the "sum total of what is known, the whole body of truth, fact, information, principles, or other objects of cognition acquired by mankind," or to "the fact or condition of apprehending truth, fact, or reality immediately with the mind or senses." *Webster's Third*

New International Dictionary 1252 (1986). Rule 702's requirement that the expert witness testify to what is "known" excludes mere unsubstantiated hypotheses or theories, however sincerely the witness may believe them.

The concept of "knowledge" about a subject, however, does not necessarily encompass only irrefutable certitudes. It would be sensible in certain contexts to refer more broadly to what is "known," as that which has been satisfactorily established for a given purpose. See *Webster's II New Riverside University Dictionary* 669 (1988). We believe that that broader meaning is more consistent with the context in which the word "knowledge" appears in Rule 702. In light of the requirement that the evidence be of such character as will "assist" the jury "to understand the evidence or to determine a fact in issue," we believe the requirement of "knowledge" should be understood to refer to the body of propositions that are at least sufficiently established to serve that purpose.

The rule of *Frye* v. *United States*, *supra*, is too limiting to serve as the exclusive test for what constitutes helpful knowledge in that broad sense. To be sure, a trial judge cannot err by *admitting* testimony that is based on the unexceptionable application of universally accepted scientific principles. But the *Frye* rule is too restrictive to serve as the sole criterion when the issue is whether evidence should be *excluded*. Evidence based on new discoveries may be demonstrably reliable on the basis of objective criteria easily understood by a trial judge. Moreover, even a body of assertions generally viewed as manifestly unreliable, untrue or even superstitious for most purposes may be sufficiently reliable to be helpful in certain limited circumstances. Thus, while a judge would err in admitting the testimony of an astrologer to prove that certain events must have occurred as predicted by the horoscope, he would be justified in admitting testimony from the same witness in order to explain the pattern underlying the crimes of a zodiac

killer. Similarly, evidence that is not sufficiently reliable to be considered helpful in proving the truth of a disputed fact may be reliable enough to impeach or corroborate the reliable evidence that *is* admissible to prove the point. Cf. *Michigan* v. *Harvey*, 494 U.S. 344, 350-351 (1990); *Oregon* v. *Haas*, 420 U.S. 714, 720-724 (1975). An epidemiological study that produces statistically insignificant results, for example, might properly be used for the limited purpose of casting doubt on a more definitive study on the same question, provided the jury receives a suitable limiting instruction. See Fed. R. Evid. 105. In sum, we believe that the *Frye* test is not sufficiently flexible to deal satisfactorily with the manifold circumstances in which specialized knowledge may be of assistance to the jury. We are therefore in agreement with those courts of appeals that have abandoned exclusive reliance on *Frye* in favor of a more generalized inquiry into the reliability of the evidence in light of the purpose for which it is offered. See *DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d at 954 ("expert testimony that is based on unreliable methodology is unhelpful and therefore excludable"); see also *United States* v. *Jakobetz*, 955 F.2d at 796.

The factors bearing on the court's determination of reliability will necessarily vary depending on the purpose for which the evidence is being offered, a matter that in turn may often depend on the requirements imposed by the relevant substantive law.[5] In the usual case involving

[5] Important environmental statutes, for example, require certain actions to be taken upon a showing that a condition creates "danger" or a "risk" of a specified consequence. See, *e.g.*, 42 U.S.C. 9606(a) ("substantial endangerment to the public health or welfare or the environment"); 42 U.S.C. 6973(a) ("upon receipt of evidence that the * * * handling, storage, treatment, transportation or disposal of any solid waste or hazardous waste may present an imminent and substantial endangerment to health or the environment, the Administrator may bring suit * * * to restrain such person * * * contributing to such handling, storage, treatment, transportation or disposal"). In such circumstances, expert testimony showing that the scientific community is sharply divided on whether the condition actually produces the specified consequence plainly would be reliable enough to be considered on the issue whether a *risk* can be demonstrated. Similarly, the governing substantive law may provide that the existence of pertinent facts must be established by reference to the latest available technology, even where that technology is in a purely developmental stage. Thus, the Clean Air Act requires that new facilties or existing facilities making major modifications demonstrate utilization of either the "best achievable [control] technology," or the "lowest achievable emission rate," depending upon whether the geographic area in which the facility is located has met primary and secondary ambient air quality standards for a given pollutant. See 42 U.S.C. 7475(a) (requiring installation of best available technology in new sources in "attainment" areas and "unclassifiable" areas); 42 U.S.C. 7479(3) (defining best available control technology); 42 U.S.C. 7501(3) (defining lowest achievable emission rate). Again, in such cases, the applicable substantive law establishes what is helpful in "determin[ing the] fact in issue." Fed. R. Evid. 702.

whether the existence of a fact can be demonstrated by the proponent, courts will ordinarily determine reliability by considering: (1) whether the technique at issue has achieved substantial acceptance by at least a significant minority within the field; (2) whether the potential rate or possibility of error can be estimated (and the extent to which any uncertainty on this score would tend to favor the opponent of the evidence); (3) the degree to which subjectivity in the analysis renders intelligent evaluation of the expert's conclusions impractical, requiring the trier to take the conclusions "on faith"; and (4) the extent to which the expert has exposed his methodology or conclusions to peers through publication or otherwise. See *United States* v. *Jakobetz*, 955 F.2d at 794, 797-798; *United States* v. *Downing*, 753 F.2d at 1238-1239; *United States* v. *Gould*, 741 F.2d 45, 49 n.2 (4th Cir. 1984); *United States* v. *Baller*, 519 F.2d at 466; see generally 3 J. Weinstein & M. Berger, *Weinstein's Evidence* ¶ 702[03], at 702-41 to 702-43 (1992) (collecting authorities).

We believe that courts should look principally to the first of these factors—the degree to which scientists have accepted the methodology—as a means of testing reliability in most cases. Judges are not better qualified to assess scientific methods than the scientific community as a whole, and they may properly view with great skepticism "a known technique which has been able to attract only minimal support within the community." *United States* v. *Downing*, 753 F.2d at 1238; see also *United States* v. *Williams*, 583 F.2d 1194, 1198 (2d Cir. 1978) ("[A] technique unable to garner *any* support, or only minuscule support, within the scientific community would be found unreliable by a court."), cert. denied, 439 U.S. 1117 (1979); 3 J. Weinstein & M. Berger, *supra*, ¶ 702[03], at 702-41 to 702-42. When a scientific technique is so novel that it has not yet been widely examined by those best qualified to identify its failings—the experts in the field—the court may admit expert testimony that relies on that technique, but only in circumstances that assure its reliability in light of the purpose for which it is being offered. See, *e.g.*, *United States* v. *Baller*, 519 F.2d at 466. If, as in this case, a scientific technique relies on statistical analysis, the proponent of the evidence must carry the burden of showing not only that the technique has an ascertainable margin of error (thereby enabling the court and the jury to weigh it intelligently), but also that the margin of error is significantly lower than what ordinarily would be expected from the operation of chance alone. A technique whose reliability is so low as to be essentially indistinguishable from throwing a die or tossing a coin cannot be the basis for rational judgment, and cannot be of assistance to the jury.

2. Our submission that a scientific methodology or technique can be considered helpful "knowledge" under Rule 702 only if that methodology or technique meets a threshold test of reliability draws additional support from Rule 703, which governs the "bases of opinion testimony

by experts." Rule 703 provides that an expert may testify to conclusions or inferences based on "facts or data" not admissible in evidence, but only if such "facts or data" are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Petitioners correctly note that Rule 703 applies only to expert witnesses who testify on the basis of hearsay evidence instead of their own first-hand observations—a subset of all expert witnesses. Pet. Br. 35. Petitioners err, however, in suggesting both that Rule 703 does not speak at all to the reliability of the methodology used by such "hearsay" experts, and that the Rule tells us nothing about the criteria for the admissibility of other expert testimony. Pet. Br. 35-37.

As to the first point, the Advisory Committee notes explain that Rule 703 is intended to "broaden the basis for expert opinions * * * and to bring the judicial practice into line with the practice of experts themselves when not in court." See Rule 703, Adv. Comm. Note. As an example, the notes refer to "a physician [who] in his own practice bases his diagnosis on information from numerous sources and of considerable variety," and who "makes life-and-death decisions in reliance upon them." *Ibid.* The physician's willingness to make such weighty decisions, however, would presumably disappear if he were required to make them based on a capriciously selected subset of the data—*e.g.*, based on patient charts from which every third entry had been deleted. That example therefore suggests that, contrary to petitioners' theory, the manner in which the facts or data are arranged—that is, the expert's method in approaching the facts or data—must itself be reliable. That conclusion is confirmed by the second example provided by the Advisory Committee, which deals with admissibility of evidence of public opinion polls. For such evidence—which relies on statistical sampling techniques very similar to those at issue in this case—the Advisory Committee expressly coun-

sels that attention should focus on "*the validity of the techniques* employed." *Ibid.* (emphasis added).

As to petitioners' second point, given that the Advisory Committee notes expressly advert to the court's authority to examine the "validity of the techniques employed" by hearsay experts, it is implausible to suggest that the drafters intended that courts would perform that function *only* for those experts, leaving other expert witnesses completely free to give testimony based even on patently absurd theories. It is far more sensible to interpret Rule 703 simply as extending to the testimony of hearsay experts the same requirements of trustworthiness otherwise required for expert testimony generally.[6] That is particularly so in light of the nearly unanimous view—requiring *some* inquiry into the foundation of scientific evidence, *e.g.*, P. Giannelli, *The Admissibility of Novel Scientific Evidence*, 80 Colum. L. Rev. 1197, 1229 (1980)—that confronted the drafters of the Federal Rules of Evidence. See *United States* v. *Abel*, 469 U.S. 45, 50-51 (1984). While it is clear enough from the language of the rules that the drafters intended to "*relax*[] the traditional barriers to 'opinion' testimony," most notably by eliminating the exclusion of opinions on "ultimate issues," *Beech Aircraft Corp.* v. *Rainey*, 488 U.S. 153, 169 (1988) (emphasis added), the proposition that they silently *eliminated* all those barriers completely, as petitioners would have it, is not only "unlikely," *United States* v. *Abel*, 469 U.S. at 50, but also basically irreconcilable with the very existence of the rules contained in Article VII of the Federal Rules of Evidence.

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[6] Indeed, there is very little particularly relevant scientific evidence that does not depend on hearsay. Most witnesses who would testify solely to the results of their own research would nonetheless necessarily rely on principles and studies—"facts or data"—developed by other scientists. In that sense, most expert opinions rely on other research, aside from the precise findings of a particular study, that are part of the "hearsay" body of scientific knowledge.

3. The general admissibility standards in the Federal Rules of Evidence provide other limitations, in addition to the requirements of Rules 702 and 703, that prevent the admission of otherwise logically relevant evidence. The most important limitation is Rule 403, which provides that relevant evidence "may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403. A district court "is accorded wide discretion in determining the admissibility of evidence" under this Rule. *United States* v. *Abel*, 469 U.S. at 54.

As petitioners concede (Pet. Br. 38-39), the general restrictions imposed by Rule 403 apply to expert testimony no less than to other types of evidence. According to the Advisory Committee notes accompanying Rule 403, the Rule authorizes exclusion of evidence where a jury might be substantially misled or confused by it, especially when the evidence tends "to suggest decision on an improper basis, commonly, though not necessarily, an emotional one." Rule 403, Adv. Comm. Note. In our view, expert testimony that is otherwise minimally reliable for a narrow, limited purpose may appropriately be excluded under Rule 403 when it is likely to confuse or mislead the jury about related issues for which it is not sufficiently reliable to be independently admissible, or when its limited relevance will be substantially outweighed by its tendency to induce an emotional, rather than a rational, judgment. Exercise of the broad authority conferred by Rule 403 may also be appropriate when a party proposes to meet his entire burden of proof through abstruse expert testimony which is at best only minimally reliable, in a case so likely to be dominated by appeals to sympathy as to create "a very real possibility of runaway emotion overcoming judgment." See, *e.g.*, *Lynch* v. *Merrell-National Laboratories*, 830 F.2d 1190, 1196-1197 (1st Cir. 1987).

4. We fundamentally disagree with a recurring theme of the argument pressed by petitioners and their amici: that the Rules of Evidence evince a plan to leave *entirely* to the jury the task of assessing the reliability of expert testimony, without any preliminary "screening" function for the court. See Pet. Br. 15, 38-40; Trial Lawyers' Amicus Br. 6-12. The Rules themselves clearly provide that all questions concerning the admissibility of evidence must "be determined by the court." Fed. R. Evid. 104(a). As this Court has made clear, that broad authority encompasses the responsibility to decide conclusively preliminary questions of fact on which the admissibility of evidence depends. See *Bourjaily* v. *United States*, 483 U.S. at 175-176 (in applying co-conspirator exception to hearsay rule, the court alone decides preliminary question of whether conspiracy existed).[7] Whether evidence

[7] We see no basis for applying a different rule when, as here, the exercise of the court's authority under Rule 104(a) "non-suits the plaintiffs." Pet. Br. 39 n.68. As Professor Morgan aptly explained in a leading article more than 60 years ago:

> It often happens that the only evidence that a litigant has to support his case is incompetent either by statute or by a rule of the common law. Where its incompetency does not depend upon the decision of a preliminary question of fact, no court allows itself to be influenced by this consideration. Granting the validity of the exclusionary rules, there is no plausible or substantial reason for discriminating between such cases and those where a preliminary investigation is necessary. The accepted theory of jury trial requires that there be submitted to the jury only matters in dispute as to which reasonable men could differ, and that in resolving the dispute the jury shall hear only legal evidence. There never was a time when every question of fact arising in a lawsuit was to be decided by the jury: nor has there been a time since the jury has been required to base its findings upon evidence submitted in open court, when it has been privileged to hear and consider all relevant evidence.

E. Morgan, *Functions of Judge and Jury in the Determination of Preliminary Questions of Fact*, 43 Harv. L. Rev. 165, 186 (1929); see generally E. Imwinkelried, *Judge Versus Jury: Who Should Decide Questions Of Preliminary Facts Conditioning The Admissibility Of Scientific Evidence?*, 25 Wm. & Mary L. Rev. 577 (1984).

is sufficiently reliable to qualify as "knowledge" under Rule 702, no less than whether the factual predicate for admissibility under a hearsay exception has been shown, is just such a preliminary question. Indeed, petitioners' contrary theory would invite extravagant efforts to introduce on behalf of defendants in criminal cases wholly unsubstantiated and speculative hypotheses, under the guise of expert scientific testimony, in an attempt to influence the jury's application of the reasonable doubt standard.[8]

Nor is there force to petitioners' argument that the doctrine of *Erie R. R.* v. *Tompkins*, 304 U.S. 64 (1938), requires that the reliability of expert testimony be left exclusively to the jury at least in diversity cases. Pet. Br. 41-46. That contention is largely based on the unwarranted assumption that abandoning the *Frye* test necessarily leaves federal courts without authority to screen the reliability of scientific testimony. As demonstrated above, and as every court to reject *Frye* has held, Rules 702, 703, 403 and 104(a) require trial courts to make an independent assessment of the reliability of scientific

[8] Petitioners' reliance on *Barefoot* v. *Estelle*, 463 U.S. 880 (1983), is misplaced. That case, which involved the constitutionality of a state evidentiary rule permitting the admission of expert psychiatric testimony on the issue of the future dangerousness of a particular person, necessarily turned on the peculiar nature of the issue on which the testimony was offered. As the Court noted, future dangerousness is the type of issue ordinarily resolved sensibly by lay people, so that it would "make little sense, if any, to submit that psychiatrists, out of the entire universe of persons who might have an opinion on the issue, would know so little about the subject that they should not be permitted to testify." *Id.* at 896-897. Contrary to petitioners' submission (Pet. Br. 39-40), the Court did not purport to decide authoritatively any issue under the Federal Rules of Evidence. On the contrary, the Court rejected a number of arguments advanced in dissent because they were based on "decisions of federal evidence law." 463 U.S. at 899 n.6.

evidence before such evidence can be submitted to the jury. Because the rules clearly speak to the issue, no *Erie* issue is presented. See *Hanna* v. *Plumer*, 380 U.S. 460 (1965) (substantially modifying "outcome-determinative" test of *Guaranty Trust Co.* v. *York*, 326 U.S. 99 (1945), on which petitioners rely); see also *Stewart Org., Inc.* v. *Ricoh Corp.*, 487 U.S. 22, 25-27 (1988). Indeed, it is quite doubtful that petitioners could succeed on their *Erie* theory even if the allocation of that traditional screening function to the court were the result of a judge-made rule. See *Byrd* v. *Blue Ridge Rural Elec. Coop., Inc.*, 356 U.S. 525, 537-538 (1958) ("The policy of uniform enforcement of state-created rights and obligations * * * cannot in every case exact compliance with a state rule * * * which disrupts the federal system of allocating functions between judge and jury.").

In sum, petitioners' fundamental premise—that rejection of the *Frye* test necessarily deprives the district courts of *any* authority to exclude unreliable testimony—is inconsistent with the language of Rules 702, 703, 403 and 104(a). Not surprisingly, petitioners' view has failed to gain any support even among the minority of courts of appeals that have rejected *Frye*. The language of those Rules makes clear that, under any formulation of the tests for assessing the admissibility of expert testimony, trial judges retain ample authority and are vested with the responsibility to exclude such testimony when it is insufficiently reliable to be helpful to the jury.

B. The Trial Court Properly Excluded The Expert Testimony Proffered By Petitioners In This Case

The court of appeals examined the admissibility of petitioners' evidence under the *Frye* rule, which it appeared to view principally as a specific application of the criteria outlined in Rule 403. See Pet. App. A2. As we have explained, it is our view that the *Frye* rule is too narrow to serve as the exclusive standard for the admissibility of expert testimony. Despite our disagreement with

the analysis employed by the court of appeals, we believe its conclusion was correct. The testimony of petitioners' experts was too unreliable to be admissible under the Federal Rules. In fact, as the district court's opinion demonstrated, and as several courts of appeals correctly have held, the methodology used by petitioners' experts was so lacking in probative value that judgment for the respondent was required as a matter of law even if the evidence had been admitted.

Petitioners' "proof" on the issue of causation fell under two main headings. First, petitioners relied on the "reanalysis" of the published epidemiological studies by three of their experts—Drs. Gross, Swan, and Glasser. The district court specifically found that those reanalyses lacked a confidence level which would render them statistically significant. Because scientific norms generally require that results be statistically significant to be considered reliable, petitioners bore a heavy burden to demonstrate that the reanalysis evidence was probative despite its failure to meet those norms. Petitioners did not, and could not, do so. To the extent the findings for the exposed population departed from the corresponding expected values, the degree of departure was consistent with what a researcher would expect based solely on the chance variability of sampling procedures. Petitioners' reanalysis evidence accordingly has no probative value in demonstrating an association between Bendectin and fetal malformation, much less that that drug "more probably than not" was the "cause" of petitioners' injuries. From the standpoint of reliability for purposes of the substantive issue in this case, those studies are not significantly better than a coin toss, and therefore could not provide a basis for expert opinion on the issue of causation.

Second, petitioners also relied on *in vitro* and *in vivo* animal tests, together with chemical structure analyses. We agree with petitioners that such tests may be useful in some limited contexts (Pet. Br. 6 nn.. 17-18), particularly in connection with *risk assessment—i.e.*, whether,

on the basis of often incomplete information, the policy considerations embodied in the substantive law counsel the taking of particular action prospectively. Cf. 21 U.S.C. 348(c)(3)(A) (so-called "Delaney Clause," which provides that "no [food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal"). The issue in this tort case, however, is significantly different. The courts below were asked to decide whether respondent's drug actually "more likely than not" caused tort injury to particular human beings. For this purpose, that type of evidence is not even logically relevant absent a foundation that at least establishes not only that human beings behave similarly to the tested animal species when exposed to a chemical, but also that the high concentrations of the chemical generally used in animal studies permit a rational extrapolation to the much lower levels to which petitioners were actually exposed. Doubtless for that reason, even petitioners' experts acknowledged the need to verify such data with epidemiological evidence. Pet. App. A3; see also *id.* at A9-A10, A13-A14. Without corroborating epidemiological evidence, those non-human studies were not "facts or data * * * of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject," Fed. R. Evid. 703, and the court of appeals therefore properly found them inadmissible. See Pet. App. A3, A9-A10, A12, A13-A14.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

WILLIAM DAUBERT AND JOYCE DAUBERT, INDIVIDUALLY AND AS GUARDIANS AD LITEM FOR JASON DAUBERT, AND ANITA DE YOUNG, INDIVIDUALLY AND AS GUARDIAN AD LITEM FOR ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

On Appeal from the United States Court of Appeals for the Ninth Circuit

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BRIEF FOR A GROUP OF AMERICAN LAW PROFESSORS AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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* Law Professors agreeing to have their names appear on this brief were solicited on the basis of their substantial scholarship in the area of scientific evidence. University affiliations are included for purposes of identification.

It should be noted that several of our colleagues felt precluded from adding their names because they had agreed to act as consultants to one of the parties to the instant case.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

No. 92-102

WILLIAM DAUBERT AND JOYCE DAUBERT, INDIVIDUALLY AND AS GUARDIANS AD LITEM FOR JASON DAUBERT, AND ANITA DE YOUNG, INDIVIDUALLY AND AS GUARDIAN AD LITEM FOR ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

On Appeal from the United States Court of Appeals for the Ninth Circuit

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BRIEF FOR A GROUP OF AMERICAN LAW PROFESSORS AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

INTEREST OF AMICI [1]

This brief is submitted on behalf of a group of law professors with strong scholarly, teaching and professional interests in the Court's interpretation of the Federal Rules of Evidence. This Brief is offered in the tradition of *amicus curiae*, with a view solely to supplying whatever assistance we can to the Court.

---

[1] Appellants and appellees have consented to the filing of this Brief and their letters of consent are being filed separately herewith.

The lower federal courts have crafted sundry ways to evaluate the admissibility of scientific information. As we map this tortured landscape, we hope to offer the Court some guidance through the thicket.

SUMMARY OF DISCUSSION[2]

Lower courts are divided on the issue of whether the Rules incorporate the common law "general acceptance" test articulated in *Frye v. United States*. In several recent cases, this Court adhered strictly to a plain-meaning approach to interpreting the Rules. An application of this approach to Rule 702 means that the *Frye* test is not incorporated in the Rules.

The proper standard under Article VII demands more than the relevancy requirement already mandated under Rule 401. Although sometimes described loosely as a "relevancy test," the standard for scientific testimony actually set out in Article VII is the helpfulness criterion stated in Rule 702: Expert testimony on "scientific" or "technical" matters must "assist the trier of fact." While helpfulness is related both to relevancy and qualifications, helpfulness is not just another word for these terms.

Courts applying Rule 702 have offered various interpretations of Article VII's helpfulness requirement. One view revisits the general acceptance test and maintains that the language of the Rules can be construed to require the test. Severe criticism of the *Frye* standard from courts and commentators should serve to caution the Court against reliance on this interpretation. The general acceptance test suffers from several fundamental weaknesses which render it susceptible to manipulation.

[2] We selected a discussion format rather than an argument format because the primary purpose of this Brief is to offer guidance on the alternatives available to the Court. We do not specifically advocate any single remedy to the questions discussed. We do, however, draw certain lessons and conclusions that we believe follow from the discussion.

Although courts have been reluctant to recognize the relationship between scientific validity and Article VII's "relevancy test," the connection is undeniable. In fact, courts regularly evaluate the validity (or what is commonly, but erroneously, called "reliability") of scientific evidence under Rule 702. If scientific information is not valid, it does not increase or decrease the likelihood of any fact in issue; invalid science does not assist the trier of fact. The special methods used by scientists, however, complicate this determination. The central question posed by this case concerns what standard judges should employ when assessing the special methods of science.

The distinct nature of scientific information provides a significant reason to apply a *de novo* standard of review. A substantial part of the inquiry is legal in character, and the factual component differs from ordinary adjudicative fact judgments in which the appellate court defers to the trial court.

If this Court determines that the validity assessment should be treated as a preliminary fact question within the trial judge's discretion, it must then decide the nature of that inquiry. The Rules provide two possibilities. Under Rule 104(a), the judge must find "preliminary facts" by a preponderance of evidence. Alternatively, under 104(b), the judge's threshold examination is limited to finding that a reasonable trier of fact could find the fact to be true. The determinative issue is whether to characterize Rule 702 as an "exclusionary rule" to which 104(a) applies or as an "inclusionary rule" to which 104(b) applies.

The statutory history of Article VII is ambiguous regarding its inclusive or exclusive character. The structure and principles underlying the Rules, however, generally support the characterization of Rule 702 as an

"exclusionary rule." Rule 104(a) ordinarily applies to circumstances presented in rules such as Rule 702, where jurors cannot be expected to make both the preliminary and ultimate findings of fact. Rule 104(a) provides the strongest judicial check and best safeguards the jurors from invalid evidence.

Requiring judges to evaluate scientific validity has raised concerns over the ability of judges to comprehend science minutiae. This concern misstates the issue. Reality dictates that someone in the adjudication process must evaluate the validity of scientific information. Judges need not become experts themselves in various scientific disciplines. Fortunately, courts and commentators have proposed numerous factors that provide substantial guidance and assistance to the courts in assessing scientific accuracy.

Subsequent to the preliminary finding of validity, Rule 403 provides a final check on the admissibility of scientific evidence. It does not impose an independent standard of validity. Rather, it excludes scientific information that, though valid, would cause inordinate prejudice or waste of time.

The final issue that must be considered by this Court is whether the *writ of certiorari* was improvidently granted in light of the substantial legislative attention now focused on the matter. The immediate need for uniformity in the Rules coupled with the significant time necessary for legislative study and action on the issue strongly suggest that this Court decide the matter.

DISCUSSION

I. DOES ARTICLE VII OF THE FEDERAL RULES OF EVIDENCE INCORPORATE THE "GENERAL ACCEPTANCE" TEST ANNOUNCED IN *FRYE v. UNITED STATES* AS THE THRESHOLD ADMISSIBILITY STANDARD FOR THE FEDERAL COURTS? [3]

Rule 702 of the Federal Rules governs the admissibility of scientific evidence in federal courts. The Rule provides for the admissibility of expert opinion when "scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue . . . ." *Fed. R. Evid.* 702. Prior to the enactment of the Rules, the courts sometimes relied on the "general acceptance" test declared in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). This test requires that, in order to be admissible, novel [4] scien-

[3] Although the first Question Presented to this Court queries whether the Federal Rules incorporate the standard established in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), the question is silent as to which rule purportedly contains it. The district court below applied *Frye* in conjunction with Rule 703 and the circuit court did not specifically locate *Frye* in Article VII. *See Daubert*, 727 F. Supp. 570, 572 (S.D. Cal. 1989); 951 F.2d 1128, 1130 n.1 (9th Cir. 1991). Courts and commentators alike tend to be imprecise in placing the *Frye* standard, but the generally prevailing view appears to situate it in Rule 702. 3 Jack Weinstein & Margaret Berger, *Weinstein's Evidence* ¶ 702[03] at 702-36 (1989); Edward J. Imwinkelried, *The "Bases" of Expert Testimony: The Syllogistic Structure of Scientific Testimony*, 67 N.C. L. Rev. 1, 1-2 (1988); *see also* Paul C. Gianelli & Edward J. Imwinkelried, *Scientific Evidence* § 1-5(F), at 29-30 (1986). *But see* Mark McCormick, *Scientific Evidence: Defining a New Approach to Admissibility*, 67 Iowa L. Rev. 879, 888 (1982) ("[R]ule 703 also may have some bearing on the issue."). As a common law standard, placing *Frye* in Article VII is not essential; as a matter of statutory interpretation, of course, it is imperative that *Frye* be pinpointed.

[4] Although the *Frye* standard applies to *novel* scientific evidence, we do not distinguish between "novel science" and "established science." Article VII also does not make this distinction.

tific evidence "must be sufficiently established to have gained general acceptance in the particular field in which it belongs." *Id.* at 1014. With the Congress' enactment of the Federal Rules, the courts have divided over whether the Rules incorporate the *Frye* test. Paul C. Gianelli & Edward J. Imwinkelried, *Scientific Evidence* § 1-5(F), at 28-29 (1986).

The Rules and their history are silent on this question. Despite the dominance of the *Frye* test at the time the Rules were considered and adopted, the Advisory Committee's Notes, the congressional committee reports and the hearings on the Federal Rules do not address the issue. *Id.* at 29. Judge Weinstein has stated that the "silence of the rule[s] and its drafters may arguably be regarded as tantamount to an abandonment of the general acceptance standard." 3 Jack Weinstein & Margaret Berger, *Weinstein's Evidence* ¶ 702[03] at 702-36 (1989). He further argues that the "[e]limination of the *Frye* test is consistent with the underlying policies of Article VII." *Id.; see also* 22 Charles Allen Wright & Kenneth W. Graham, *Federal Practice and Procedure* § 5169, at 92 (1978) (concluding that *Frye* was repealed by the Federal Rules).

Some commentators disagree with Judge Weinstein's view. *See e.g.*, 1 David Louisell & Christopher Mueller, *Federal Evidence* § 105, at 818 (1977); Michael H. Graham, *Handbook of Federal Evidence* § 703.2 (3d ed. 1991). While Professors Louisell, Mueller and Graham criticize the *Frye* standard, they conclude that it survived enactment of the Rules. It was the only standard in common use and the Rules invite (if not require) some standard. Furthermore, it is argued that imposition of the *Frye* test provides a method by which courts can assess the validity of novel scientific information and safeguards the jury against possibly specious expert testimony. *United States v. Downing*, 753 F.2d 1224, 1235 (3d Cir. 1985).

This Court has not, however, looked to the common law prior to the enactment of the Federal Rules to find their meaning. Instead, this Court has employed the plain-meaning standard in its construction of the Rules. This standard "requires courts to enforce a statute's literal language unless the legislative history intended another meaning." Randolph N. Jonakait, *The Supreme Court, Plain Meaning, and the Changed Rules of Evidence*, 68 Tex. L. Rev. 745, 746 (1990). In several recent cases this Court has adhered strictly to a plain-meaning approach to interpreting the Rules. *See Bourjaily v. United States*, 483 U.S. 171, 179-81 (1987); *Huddleston v. United States*, 485 U.S. 681, 687 (1988). *But see Green v. Bock Laundry Machine Co.*, 490 U.S. 504, 527 (1989) (Scalia, J., concurring) (the Court will go beyond the plain meaning when "a statute which, if interpreted literally, produces an absurd and perhaps unconstitutional result").

A plain-meaning interpretation of the language of Rule 702 and its statutory history means that the *Frye* test is not incorporated in the Rules. Neither the *Frye* test nor the concept of "general acceptance" appear in the text of Article VII. The evidentiary concerns subsumed in the *Frye* test and enumerated by many courts and commentators may be important factors to be considered in establishing a sound evidentiary system; however, they are not part of the language of the Rules and their statutory history.

II. WHAT IS THE PROPER STANDARD OF ADMISSIBILITY OF SCIENTIFIC EVIDENCE UNDER THE FEDERAL RULES?[5]

Although the standard for scientific evidence under Article VII of the Federal Rules is often described as a

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[5] Although this is a civil case, we take note of the fact that whatever interpretation of Article VII this Court chooses will also apply to criminal cases. Rule 702 does not distinguish between civil and

"relevancy test," such a limited characterization constitutes a mere redundancy. Rule 401 already requires, as a threshold matter, that all evidence be relevant to be admitted. Rule 702 focuses the relevancy requirement on the scientific merit [6] of the evidence and expressly mandates that the scientific information "assist the trier of fact." [7] In general, under the Rules all relevant evidence is admitted and the opponent of the evidence bears the burden to provide a good reason to exclude it. In some instances, however, as with hearsay, more is needed to

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criminal cases and, we believe, the threshold admissibility standard should be essentially the same in both contexts. This is not to say, however, that the same evidence might not, ultimately, be treated differently in the two contexts: the danger of unfair prejudice might be much greater in the criminal context from a particular scientific method and thus lead to a different result under Rule 403. *See infra* § II(D). In addition, the present action does not implicate constitutional concerns as might arise in the criminal context when a defendant offers scientific information in his or her defense. *See generally Chambers v. Mississippi*, 410 U.S. 284 (1973).

[6] The discussion herein applies to *all* expert testimony premised upon purportedly scientific methods. Some state courts draw a distinction between expert testimony and scientific evidence, *see e.g., People v. McDonald*, 690 P.2d 709, 723-24 (Cal. 1984) and others draw a distinction between social science and natural science. *See e.g., People v. Stoll*, 783 P.2d 698, 712-13 (Cal. 1989). Such distinctions are unsound as a matter of logic and practice. *See* David L. Faigman, *To Have and Have Not: Assessing the Value of Social Science to the Law as Science and Policy*, 38 Emory L.J. 1005, 1024-25 (1989). Moreover, neither *Frye*, as interpreted by most federal courts, nor the plain language of Article VII of the Rules, draw these distinctions.

[7] Of course, Rule 702 is not limited to the scientific context, for it also applies to "technical or other specialized knowledge." The present discussion is limited to the scientific context because that is the nature of the expertise offered here. Nonscientific expertise presents many similar problems, as well as many special ones, that space does not allow us to consider. *See generally* Charles T. McCormick, *McCormick on Evidence* § 13, at 33-34 (Edward W. Cleary *et al.* eds., 3d ed. 1984).

admit the evidence.[8] As the lower courts have demonstrated, multiple ways exist to interpret what more is needed under Article VII. The remainder of this Brief considers these alternatives and the consequences that follow from each.

A. Does Rule 702 Require Merely That the Witness Be "Qualified"?

Many observers of Rule 702's "relevancy test" have concluded that judges applying the Rule do little more than check the qualifications of the experts. *See, e.g.*, Paul C. Gianelli, *The Admissibility of Novel Scientific Evidence:* Frye v. United States, *A Half-Century Later*, 80 Colum. L. Rev. 1197, 1210 (1980). Commentators have noted that Article VII plainly demands more. *See* Edward J. Imwinkelried, *The "Bases" for Expert Testimony: The Syllogistic Structure of Scientific Testimony*, 67 N.C. L. Rev. 1, 14 (1988). Merely checking qualifications confuses expertise with experts. Having earned the appropriate degrees from a particular discipline does not ensure that the "expert" will provide any assistance to the trier of fact. *United States v. Tranowski*, 659 F.2d 750, 755 (7th Cir. 1981). In effect, judges who only check qualifications defer to the professional guilds to decide what scientific evidence to admit. *See* Comment, *The Psychologist as Expert Witness*, 38 Md. L. Rev. 539, 563-64 (1979). Admissibility of scientific evidence thus

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[8] The Petitioner's second Question Presented raises the issue of the power of lower federal courts under Rule 402's mandate that all relevant evidence is admissible unless excluded pursuant to another rule. We do not disagree with the proposition that Rule 402 was intended to restrict the federal courts' common law making power over the rules of evidence. 22 Charles Allen Wright & Kenneth W. Graham, Jr., *Federal Practice and Procedure: Evidence* § 5192, at 177 (1978). However, regarding the interpretation of Rule 702, the principal question of concern here, Rule 402 provides little guidance. Rule 702, after all, is one of those "other rules" that restrict the admission of "relevant evidence." *See Downing*, 753 F.2d at 1224.

becomes a guild issue resolved not by legal principle, nor on the basis of the accuracy of the information, but instead by the internal politics of professional organizations. *See* David L. Faigman, *To Have and Have Not: Assessing the Value of Social Science to the Law as Science and Policy*, 38 Emory L.J. 1005, 1086 (1989).

To be sure, the qualifications of experts are an explicit and integral component of the threshold inquiry under the Rules. But failure to query more than qualifications at the courthouse door leads inevitably to the admission of invalid science.

B. Do the Federal Rules Contain a "General Acceptance" Standard?

Even if the drafters did not specifically intend to incorporate the *Frye* test into the Federal Rules, the Rules might, nonetheless, contain a general acceptance standard. For instance, Rule 702's requirement that the evidence assist the trier of fact might be construed to require that scientists agree among themselves that the evidence is of assistance before it is presented to the jury.[9]

Severe criticism of the general acceptance test from courts and commentators should serve to caution this Court from interpreting the vague language of Article VII to require the general acceptance test. *See generally Downing*, 753 F.2d at 1235-37. The significant vagueness of the test renders it susceptible to manipulation and tends to obscure the relevant inquiry. *Id.* at 1236. Since the test serves as a proxy for determining the validity[10] of the scientific method, technique or opinion

[9] The general acceptance standard, in principle, applies to the scientific *methodology* used rather than the specific conclusions derived from that methodology. *See Ibn-Tamas v. United States*, 407 A.2d 626, 638 (D.C. App. 1979). The admitting court, of course, still must check that the generally accepted method was *actually* employed to obtain the proffered results.

[10] Courts use the term "reliability" to refer loosely to what scientists separate into validity and reliability. Unfortunately, the use of different terms injects unnecessary confusion into the debate. We use the standard scientific definition of validity so as to create some consistency across the law and science frontiers; this area of the law would be substantially assisted if lawyers and scientists began using the same vocabulary. "Validity" refers to the ability of a scientific test to measure what it purports to measure; "reliability" refers to the ability of a scientific test to obtain consistent results. Paul C. Gianelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States, A Half-Century Later*, 80 Colum. L. Rev. 1197, 1201 n.20 (1980). Consider the example of the polygraph. While a "lie-detector" may be *reliable* in measuring differences in skin conductivity, pulse, respiration and temperature, its *validity* has been challenged on the basis that the relationship between measurable physical changes and lying is uncertain and varies widely among people and circumstances. *See United States v. Williams*, 737 F.2d 594, 611 (7th Cir. 1984). *See generally* Faigman (1989), *supra*, at 1010 n.16. The pertinent question of admissibility is validity. *See* D. Michael Risinger, Mark P. Denbeaux & Michael J. Saks, *Exorcism of Ignorance as a Proxy for Rational Knowledge: The Lessons of Handwriting Identification "Expertise"*, 137 U. Pa. L. Rev. 731, 737 (1989) (In a proficiency test sponsored by the Forensic Sciences Foundation, handwriting experts unanimously agreed on the solution to a handwriting identification problem (100% reliability), but all of them reached an incorrect result (0% validity).).

in question, its utility can best be evaluated on the basis of its success in this capacity.

The general acceptance test suffers from several fundamental weaknesses. It is often criticized as overly conservative, Louisell & Mueller, *supra*, § 105, at 821-22, for it imposes a protracted waiting period that valid scientific evidence and techniques must endure before gaining legal acceptance. *See* Gianelli (1980), *supra*, at 1223; *see also United States v. Addison*, 498 F.2d 741, 743 (D.C. Cir. 1974). Other weaknesses of the general acceptance test concern the problem of ascertaining when a scientific proposition has been generally accepted. There are no standards defining the "pertinent field" to be consulted and nothing in the test to establish what proportion of experts constitute "general acceptance." *See e.g., United States v. Williams*, 583 F.2d 1194, 1198 (2d Cir. 1978), *cert. denied*, 439 U.S. 1117 (1979).

The courts have had considerable difficulty defining the "pertinent field" in which to assess the scientific information because it often extends into more than one academic or professional field. Gianelli (1980), *supra*, at 1208. Compounding this problem is that each field may contain one or more subspecialty. *Id.* at 1209. Although in theory general acceptance is the most conservative test of admissibility, in practice it often results in the most liberal standards of admission. The narrower a court defines the pertinent field, the more agreement it is likely to find. *See Williams*, 583 F.2d at 1198 (noting that "[s]election of the 'relevant scientific community,' appears to influence the result"). Even tea-leaf reading is generally accepted if the pertinent field is practicing tea-leaf readers. The general acceptance test thus degenerates into a process of counting noses. *DeLuca v. Merrell Dow*, 911 F.2d 941, 955 (3d Cir. 1990). Because the pertinent field can be readily manipulated, the test by itself provides little bulwark against shoddy science.

An essential premise of the general acceptance test is that if the scientific community does not agree on the accuracy of scientific information a jury can hardly be expected to resolve the dispute. *Barefoot v. Estelle*, 463 U.S. 880, 929 (1983) (Blackmun, J., dissenting). At the same time, the rule cannot demand consensus, for the nature of the scientific enterprise is dynamic. *See Williams*, 583 F.2d at 1198. While scientists might agree on many propositions, debate, disagreement and constant skepticism are the hallmarks of good science. Therefore, the meaning of general acceptance of scientific methods remains vague: if consensus were the standard, little scientific information would make it through the courthouse door; and if the Rules admit scientific information that is the subject of substantial disagreement, juries are left to answer questions scientists cannot solve."[11]

[11] These criticisms of the general acceptance test do not mean that the views of the "pertinent field" should be ignored. Given the limited time and expertise of judges in evaluating scientific information, they should consider all relevant input regarding the validity of the science. *See infra* § II(C)(3).

C. Does Article VII's Relevancy Test Require the Judge To Conduct a Preliminary Review of the Validity of the Scientific Information?

In addition to the requirement that the expert be qualified, Rule 702 also expressly directs that the expert's testimony "assist the trier of fact." This standard is generally interpreted as creating a "relevancy test." As noted above, in order to avoid redundancy with Rule 401, Rule 702's relevancy test is directed at the probative *scientific* value of the evidence.[12]

Although courts have been reluctant to recognize the relationship between scientific validity and legal relevance, the connection is undeniable. *See* Gianelli & Imwinkelried, *supra*, § 1-6(A), at 32 ("The probative value of scientific evidence depends on its reliability."); Faigman (1989), *supra*, at 1081 ("The *legal relevance* of social science research simply cannot be divorced from its *scientific credibility*."). Indeed, from a scientific standpoint, relevance is synonomous with validity. Notwithstanding their protestations to the contrary, courts regularly evaluate the validity of scientific evidence under Rule 702's relevancy test.

[12] Some courts find implicit in Rule 702 the requirement that the expert testimony must be "beyond the ken of the average layperson" to be admitted. *See McCormick on Evidence*, *supra*, § 206, at 623; *see also United States v. Fosher*, 590 F.2d 381, 383 (1st Cir. 1979); *United States v. Thevis*, 665 F.2d 616, 641 (5th Cir. 1982). In one respect, this view is correct in that ordinarily scientific evidence will be helpful *because* it applies to a subject jurors know nothing about. Courts, however, have consistently interpreted Rule 702's helpfulness test liberally so as to allow experts to testify also to subjects that jurors already know something about. 2 Stephen A. Saltzburg & Michael M. Martin, *Federal Rules of Evidence Manual* 13 (5th ed. 1990) ("[A]n expert can be employed if the expert's testimony will be helpful to the trier of fact in understanding evidence that is simply difficult, [though] not beyond ordinary understanding.").

Suppose a tea-leaf reader, educated and licensed by the appropriate organizations, offers to testify that after reading the plaintiff's tea-leaves he or she concludes that Bendectin caused the plaintiff's birth defects. Obviously, the tea-leaf reader will not be permitted to testify. But why is this obvious? The tea-leaf reader's testimony is "relevant," in that he or she will testify specifically on the issue in dispute. Courts do not permit tea-leaf readers to testify because they do not find this testimony credible; it is not sufficiently "valid." Tea-leaf reading, of course, is an extreme case and it was selected merely to illustrate the point. Still, too much "science" introduced in to American courtrooms is about as valid as tea-leaf reading.[13]

In order to identify the appropriate meaning of "relevance" in Rule 702, it is helpful to consider the meaning of this term as it is understood generally in the law of evidence. The concept of relevance actually contains two components: materiality and probative value. Materiality depends upon the legal issue before the court: "What is 'in issue,' that is, within the range of the litigated controversy, is . . . controlled by the substantive law." Charles T. McCormick, *McCormick on Evidence* § 185, at 541 (Edward W. Cleary *et al.* eds., 3d ed. 1984); *see also* Laurens Walker & John Monahan, *Social Facts: Scientific Methodology as Legal Precedent*, 76 Cal. L. Rev. 877, 883 (1988). The tea-leaf reader's testimony is thus "relevant" because it is "material" to a fact in issue. The second component of "relevance" is "probative value" or "logical relevance." Richard Lempert &

[13] The distinguished physicist Richard Feynman described such "science" as "cargo cult science." According to Professor Feynman, after World War II certain Pacific Islanders wanted the cargo planes to keep returning. These islanders made runways, stationed a man with wooden headphones and bamboo for antennas, lighted some fires and waited for the planes to land. Cargo cult scientists act in the same way. "They follow all the apparent precepts and forms of scientific investigation, but they're missing something essential because the planes don't land." *N.Y. Times*, Feb. 17, 1988 at A1.

Stephen A. Saltzburg, *A Modern Approach to Evidence* 153 (2d ed. 1982) (evidence is relevant if it "tends logically to prove or disprove some fact in issue"). It is this component that relates directly to scientific validity. If scientific information is not valid, it does not increase or decrease the likelihood of any fact in issue.

The matter of relevance is complicated in the Article VII context, however, due to the special methods used by scientists to assess validity. In the following section of this Brief we consider how thorough judges must be in assessing these special methods under the Rules and whether they are up to the task.

1. *Is the validity of scientific information to be decided as a matter of law under Rule 702 and subject to a* de novo *standard of review on appeal?*

The Ninth Circuit below held that the question of the validity of scientific information "is reviewed *de novo* by an appellate court, for '[t]he answer to the question about the reliability of a scientific technique or process does not vary according to the circumstances of each case. It is therefore inappropriate to view this threshold question of reliability as a matter within each trial judge's individual discretion.'" *Daubert*, 951 F.2d at 1130, *quoting Reed v. State*, 391 A.2d 364, 367 (Md. 1978); *see also Williams*, 583 F.2d at 1197-1201.

Although trial courts are invested with wide discretion when applying the Rules, *Hamling v. United States*, 418 U.S. 87, 108 (1974), significant reasons support limiting their discretion regarding validity assessments. First, a substantial component of the "relevance" determination under Rule 702 is legal in character: "The Court has long noted the difficulty of distinguishing between legal and factual issues." *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 401 (1990); *See* Mark McCormick, *Scientific Evidence: Defining a New Approach to Admissibility*, 67 Iowa L. Rev. 879, 908 (1982) (describing the

question of the admissibility of novel scientific evidence as "a mixed question of law and fact"). Moreover, the factual component of the determination is not the traditional case-specific adjudicative fact to which an appellate court defers to the trial court's findings. *Compare* Kenneth Culp Davis, *An Approach to Problems of Evidence in the Administrative Process*, 55 Harv. L. Rev. 364, 402-03 (1942) (describing and contrasting adjudicative facts and legislative facts) *with* Laurens Walker & John Monahan, *Social Frameworks: A New Use of Social Science in Law*, 73 Va. L. Rev. 559, 563-70 (1987) (modifying and expanding the concept of adjudicative facts). Trial courts are not necessarily better situated to assess the validity of scientific methods. M. McCormick, *supra*, at 909. Such determinations do not, for instance, depend on observing the demeanor of witnesses or knowledge of local conditions.

Scientific methods ordinarily operate at two fact-levels of the trial process. Scientific information both transcends individual disputes and is specific to particular disputes. *See* John Monahan & Laurens Walker, *Social Authority: Obtaining, Evaluating and Establishing Social Science in Law*, 134 U. Pa. L. Rev. 477, 490-91 (1986); *see also* Imwinkelried (1988), *supra*, at 24-25. The *de novo* standard should apply to scientific information that transcends a particular dispute. *See Dunagin v. City of Oxford, Miss.*, 718 F.2d 738, 748-49 n.8 (5th Cir. 1983). Such facts resemble legislative facts much more than adjudicative facts; this Court has historically reviewed legislative facts on a *de novo* standard of review. *See e.g., New York v. Ferber*, 458 U.S. 747, 758 n.9 (1982) (the effect on children of being a subject in pornographic materials); *see generally* David L. Faigman, *"Normative Constitutional Fact-Finding": Exploring the Empirical Component of Constitutional Interpretation*, 139 U. Pa. L. Rev. 541, 552-56 (1991).

An example that illustrates the law-science connection is research on the effects of cigarette smoking on health

in litigation against cigarette producers. A substantial body of research indicates that cigarette smoking significantly increases a person's risk for lung cancer. This research transcends particular disputes and ought to be subjected to *de novo* review; there is no reason to allow different courts to decide this matter differently. *Cf. United States v. Jacobetz*, 955 F.2d 786, 799 (2d Cir. 1992) (taking judicial notice of the general acceptance of the theory underlying DNA profiling and the general techniques used to identify profiles). In addition, the plaintiff will probably offer an expert to testify that the *plaintiff's* lung cancer was caused by cigarette smoking.[14] This testimony has two components. *See* Walker & Monahan (1987), *supra*, at 584; *see also* Robert P. Mosteller, *Legal Doctrines Governing the Admissibility of Expert Testimony Concerning Social Framework Evidence*, 52 Law & Contemp. Probs. 85 (1989). First, it is premised upon the transcendent scientific conclusion that experts can accurately draw such inferences. This scientific premise also should be subject to a *de novo* standard of review. Second, it is premised upon the conclusion that the particular witness is competent to make such a judgment; this assessment is case specific and should be overturned only if the trial judge abused his or her discretion in admitting it. *See Jacobetz*, 955 F.2d at 799 (leaving the reliability of the specific DNA profile used in the case for the jury to determine).

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[14] Not all scientific information is described at the case-specific level at trial. For example, experts who testify on the unreliability of eyewitness identifications present only general research findings indicating the factors related to errors in witnesses' perceptions. The jury is left to draw inferences from the expert's testimony to the case before it. *See e.g., Arizona v. Chapple*, 660 P.2d 1208, 1219 (Ariz. 1983) (concluding that the fact that the expert "would testify to general factors which were applicable to this case . . . , but would not express any opinion with regard to the accuracy of the specific identification," favored admissibility); *see generally* John Monahan & Laurens Walker, *Social Science in Law: Cases and Materials* 346-448 (1990).

Application of less than a *de novo* standard of review to scientific information that transcends individual cases invariably leads to inconsistent treatment of similarly situated claims. The validity of scientific knowledge does not change from court to court; assessments of that knowledge also should not change from court to court.

If scientific knowledge that transcends particular disputes is reviewed under Rule 702 as a matter of law, trial courts must follow established precedent on the issue; if it is a matter of first impression, of course, the trial court must exercise its independent legal judgment. If this Court, however, determines that the validity assessment should be treated more conventionally as a preliminary fact question within the discretion of the trial court, Rule 104 guides the lower court's assessment. We now turn to the question of the nature of that assessment.

2. *Should courts assess the validity of scientific evidence under the 104(a) or under the 104(b) threshold standard of review?*

Judges regularly make factual judgments when applying the Rules. Rule 104 sets forth the two basic types of judgments that judges are called upon to make when evaluating the admissibility of evidence. Rule 104(a) provides that when a fact is a prerequisite to the application of a Rule, the judge must independently find the existence of that fact. *McCormick on Evidence*, *supra*, at 135-37. Judges must find "preliminary facts" under Rule 104(a) by a preponderance of the evidence. *Bourjaily v. United States*, 483 U.S. 171 (1987). Alternatively, when the relevance of testimony depends on the existence of a fact or facts, under 104(b) the judge's threshold examination is limited to finding that a reasonable trier of fact could find the fact to be true. *Huddleston v. United States*, 485 U.S. 681 (1988). This part considers which section of Rule 104 applies to the validity determination to be made under the Rule 702 relevancy test.

McCormick's excellent discussion of the distinctions in application between Rules 104(a) and (b) points out that under 104(a) "the trial judge decides with finality those preliminary questions of fact upon which depends the admissibility of an item of evidence that is objected to under an exclusionary rule of evidence." *McCormick on Evidence*, *supra*, at 135 (footnote omitted). Thus, for example, Rule 104(a) requires judges to independently find under Rule 804(b)(2) that a dying declaration was made under a belief of impending death before permitting the jury to consider the hearsay statement. Rule 104(b), in contrast, applies in those situations "in which the relevancy, i.e. probative value, of a fact offered in evidence depends on the existence of another, and preliminary, fact." *Id.* at 137.

Two recent decisions of this Court adhere to and exemplify the distinct provisions of Rule 104. In *Bourjaily v. United States*, this Court applied the 104(a) standard to the preliminary question whether a conspiracy existed under the hearsay exclusion for the statements of coconspirators. 483 U.S. at 171 (applying Rule 104(a) to *Fed. R. Evid.* 801(d)(2)(E)). Consistent with the traditional standard for preliminary fact review for exclusionary rules of evidence, *Bourjaily* required judges to independently find the existence of a conspiracy by a preponderance of the evidence. In *Huddleston v. United States*, however, this Court did not apply the 104(a) standard to extrinsic act evidence under 404(b). This Court found that Congress' principal concern in enacting Rule 404(b) was not exclusion, but rather "ensuring that restrictions would not be placed on the admission of such evidence." 485 U.S. at 689. Thus, this Court read 404(b) as a rule of inclusion and applied Rule 104(b). *Id.* at 687 ("Generally, . . . Rules [404 through 412] do not flatly prohibit introduction of such evidence but instead limit the purpose for which it may be introduced.").

The determinative issue, therefore, concerns whether to characterize Rule 702 as an "exclusionary rule" to which

104(a) applies or as an "inclusionary rule" to which 104(b) applies.[15] Several factors need to be considered in determining the evidentiary character of Rule 702, including its statutory history, the structure of the Federal Rules and the purposes underlying the Rule's enactment.

The statutory history of Rule 702 is ambiguous regarding its inclusive or exclusive character. As most commentators agree, Article VII was, in part, a reaction to the perceived conservative standard of *Frye*. *See* Paul C. Gianelli, *General Acceptance of Scientific Tests*—Frye *and Beyond, in Scientific and Expert Evidence* 11, 20-30 (Edward J. Imwinkelried ed., 2d ed. 1981). Moreover, the general tenor of the Federal Rules favors admissibility of relevant evidence. *See e.g., Fed. R. Evid.* 402. At the same time, the drafters of Article VII explicitly stated that the Rules should not be so liberally construed that they "break down the rules of exclusion unduly." *Fed. R. Evid. 703 Advisory Committee's Note*; *see also Fed. R. Evid. 706 Advisory Committee's Note* ("The practice of shopping for experts, the venality of some experts, and the reluctance of many reputable experts to involve themselves in litigation, have been matters of deep concern."). Article VII, therefore, was intended to liberalize the admissibility standard of *Frye* but not open the floodgates to all experts dressed in the guise of science.

The structure and principles underlying the Rules generally support application of 104(a) to admissibility questions under 702. Although the Rules support a liberal admissibility standard as reflected in Article IV, the subsequent Articles substantially limit this principle. In

[15] Many scholars have interpreted the proposed revision to Rule 702, discussed *infra*, to create just such a requirement. *See* Ronald L. Carlson, *Experts as Hearsay Conduits: Confrontation Abuses in Opinion Testimony*, 76 Minn. L. Rev. 859, 871-72 (1992); David L. Faigman, *Struggling to Stop the Flood of Unreliable Expert Testimony*, 76 Minn. L. Rev. 877, 885-86 n.41 (1992).

particular, Articles VI, VII and VIII designate whole areas in which otherwise relevant evidence is excluded. Judges are charged with the responsibility for applying these exclusionary rules for good reasons. Jurors are not presumed to be capable of doing the mental gymnastics necessary to assess both admissibiilty and weight; jurors who determine that evidence is not admissible are thought, nonetheless, to put some weight on what they have heard. *See* John Kaplan, *Of Mabrus and Zorgs*, 66 Cal. L. Rev. 987, 997-99 (1978) (criticizing the California Rule for giving these sorts of fact questions to jurors and praising the Federal Rules for treating them as preliminary facts to be decided by judges). Thus, the more stringent 104(a) standard ordinarily applies to the application of exclusionary rules under circumstances when the jury cannot be expected to make both the preliminary and ultimate findings of fact. Rule 702 presents such an instance. Jurors obligated to conduct the initial validity assessment are unlikely to be able to ignore the dubious message of invalid science. Indeed, "novel scientific evidence carries with it concerns over trustworthiness and reliability akin to those raised by offers of hearsay evidence." *Downing*, 753 F.2d at 1240 n.21; *see generally* Peter Tillers & David Schum, *Hearsay Logic*, 76 Minn. L. Rev. 813 (1992). Moreover, many have voiced the concern that jurors will be overwhelmed by the aura of infallibility of scientific evidence, *Barefoot*, 463 U.S. at 926 (Blackmun, J., dissenting); and thus jurors cannot be expected to conduct such a preliminary assessment very well. For these reasons, the judge should guard the courthouse door to ensure that only valid science is admitted. *See Tranowski*, 659 F.2d at 755 (applying Rule 104(a) to assess the validity of the data upon which the expert relied).

Finally, the plainly stated purpose of Rule 702 is to "assist the trier of fact." Implicit in this mandate lies the lesson that judges are to play *some* supervisory role over scientific evidence. In order for this role to have

meaning, judges must independently assess the validity of the scientific evidence. Rule 104(a) provides the strongest judicial check on the vagaries of scientific practice and the best safeguard against jurors being overwhelmed by those practices.

Taking the opposite approach to the validity question would involve the jury under Rule 104(b) in doing something it cannot do well.[16] The latter provision relates to commonsense logic that is the standard of "relevancy" set forth in Rule 401. But the scientific validity standard required by the helpfulness criterion in Rule 702 is not a matter of commonsense judgment. Indeed, the hallmark of science is *not* to trust "commonsense," but rather to test it. Science subjects theories, hypotheses and commonsense to systematic test. This testing distinguishes science from commonsense; and a scientist's claim to expertise depends on his or her adherence to established methods of empirical investigation. *See* Faigman (1989), *supra*, at 1014-21; *cf.* Ronald L. Carlson, *Policing the Bases of Modern Expert Testimony*, 39 Vand. L. Rev. 577, 580 (1986). Under Rule 104(b) the court still must

[16] Professor Edward Imwinkelried, *Judge Versus Jury: Who Should Decide Questions of Preliminary Facts Conditioning the Admissibility of Scientific Evidence?*, 25 Wm. & Mary L. Rev. 577 (1984), concluded that although a 104(a) standard was preferable, the Rules currently mandate only a 104(b) evaluation of scientific validity. Imwinkelried relies on his reading of Rule 901 which, he believes, makes the preliminary finding regarding validity of the scientific process a matter of conditional relevancy. Space does not permit a full response to this unique approach; Judge Becker, however, considered and rejected this view in *Downing*. 753 F.2d at 1240 n.21; *see also McCormick on Evidence* 885 n.6 ("The emphasis of Rule 901 is upon showing that the offered item [e.g., a computer printout] . . . is what it is claimed to be, i.e., that it is genuine . . . rather than that what is in the [computer] is correct."). We join Judge Becker and the Third Circuit in their evaluation of the Imwinkelried view: "We share his view on the need for certain safeguards against unreliable scientific evidence, but dispute the proposition that an amendment to the evidence rules is required to implement them." *Downing*, 753 F.2d at 1241 n.21.

evaluate the foundation supporting the proffered scientific information. It differs from Rule 104(a) only in the level of confidence the judge must have in her determination regarding the validity of the science. Rule 104(b), therefore, does not free the judge from the responsibility for making an independent assessment that a reasonable juror could find the information valid. *See Huddleston*, 485 U.S. at 689-91.

3. *Do judges have the capacity and resources to review the scientific validity of expert testimony?*

Because the Rules require the judge to evaluate the validity of scientific information, the question naturally arises whether judges *can* conduct this inquiry. *See* 3 Weinstein & Berger, *supra*, ¶ 702[03], at 702-34 to 702-35 (recognizing the necessity of assessing "validity" in order to evaluate relevancy, but noting that "the court almost never will have sufficient personal expertise to evaluate the validity of the new development"). Indeed, many courts have expressed discomfort at having to review the methodological and, in particular, statistical underpinnings of scientific research. *See e.g., Craig v. Boren*, 429 U.S. 190, 204 (1976) ("It is unrealistic to expect either members of the judiciary or state officials to be well versed in the rigors of experimental or statistical technique."); *see also State v. Dean*, 307 N.W.2d 628, 646 (Wis. 1981) ("[The] burden on the trial court to assess polygraph evidence may outweigh any probative value the polygraph evidence may have."); *Ethyl Corp. v. EPA*, 541 F.2d 1, 67 (D.C. Cir. 1976) (Bazelon, C.J., concurring) ("[S]ubstantive review of mathematical and scientific evidence by technically illiterate judges is dangerously unreliable. . . .").

Presenting the problem as concern over the ability of judges to comprehend science minutiae, however, misstates the issue. First, even the most difficult concepts used by scientists in the legal forum are no more ab-

struse than the more esoteric concepts judges employ regularly. Monahan & Walker (1986), *supra*, at 511 n.119. Moreover, the reality is that *someone* in the process must evaluate the validity of scientific evidence. Part of a juror's duty to *weigh* scientific evidence includes an assessment of its validity. If jurors can evaluate validity there is little reason to believe judges cannot be as capable in this matter. In fact, there is some reason to believe judges will develop facility with scientific techniques over time. As judges increasingly confront the scientific method, their confidence and sophistication with these methods will grow. *See* Judge Leventhal's response to Judge Bazelon, *supra*, in *Ethyl Corp.*, 541 F.2d at 69 (Leventhal, J., concurring) ("The aim of the judge is not to exercise expertise or decide technical questions, but simply to gain sufficient background orientation. Our obligation is not to be jettisoned because our initial technical understanding may be meagre when compared to our initial grasp of FCC or freedom of speech questions.").

To say that judges must achieve an understanding of science does not mean that they must become experts themselves in the sundry scientific disciplines that come into court today. Instead, judges must familiarize themselves with the generally applicable techniques used to critically examine the validity of a particular theory or method. Several courts and commentators have suggested factors that the sophisticated court could examine in making such an assessment. In *Downing*, the court identified eight considerations relevant to an assessment of scientific accuracy: (1) the degree of acceptance within the scientific community, (2) the novelty of the technique, (3) the existence of specialized literature dealing with the technique, (4) the qualifications and professional stature of the expert witness, (5) the non-judicial uses to which the scientific technique is put, (6) the frequency with which the technique leads to erroneous results, (7) the type of error generated by the technique,

and (8) any expert testimony that has been offered in earlier cases to support or dispute the merits of a particular scientific procedure. 753 F.2d at 1238-39. Similar factors have been suggested by numerous commentators. *See e.g.*, Weinstein & Berger, *supra*, ¶ 702[03], at 702-41 to 702-42 (listing seven factors); M. McCormick, *supra*, at 911-12 (1982) (listing eleven factors); Bert Black, *A Unified Theory of Scientific Evidence*, 56 Fordham L. Rev. 595, 642-43 n.258 (1988) (listing four of the factors proposed by the 1983 National Conference of Lawyers and Scientists); Monahan & Walker (1986), *supra*, at 498-512 (articulating guidelines for evaluating social science authority). Rule 702's relevancy standard requires courts to assess the validity of scientific information; a court should rely on a multitude of factors to assist it in that determination. Although it is beyond the scope of this Brief to state and analyze all of the possible factors that judges could consider in determining validity, it is clear that substantial guidance does exist to assist judges in assessing validity.[17]

A significant issue raised in the petition for *certiorari* concerns what part peer review should play in determining admissibility. We agree that courts should not wholly delegate responsibility to the editors of scientific journals. Peer review suffers too many limitations to be, by itself, a litmus test for the admissibility of scientific information. *See* Charles W. McCutchen, *Peer Review: Treacherous Servant, Disastrous Master*, Tech. Rev. 28 (Oct. 1991). Nonetheless, research subjected to peer review undergoes a level of scrutiny that non-reviewed research

[17] Rule 706 provides judges with a mechanism by which expert witnesses can be appointed to assist them with the intricacies of scientific information. Unfortunately, as a recent study by the Federal Judicial Center indicates, Rule 706 has not proved very helpful to judges. Joe S. Cecil and Thomas E. Willging, *Defining a Role for Court-Appointed Experts*, 4 FJC Directions 6 (1992) (finding, among other things, that only 20% of judges surveyed had ever appointed experts under Rule 706).

does not. *See* Arnold S. Relman & Marcia Angell, *How Good is Peer Review?*, 321 New Eng. J. Med. 827, 828 (1989). Courts must, to the extent practicable, independently evaluate all evidence proffered; evaluating the validity of scientific information will entail consultation of a variety of authorities. Whether research survived peer review should be just one factor among many that courts consider when examining the validity of scientific information.

To be sure, applying a Rule 104(a) threshold evaluation will not eliminate all of the problems inherent in the examination of scientific techniques in the legal setting. It does, however, provide judges with a principled method for recognizing and guarding against shoddy science. As Professors John Monahan and Laurens Walker noted, "[i]t would be foolish to suggest that all social science studies can be adequately evaluated by reference to a simple checklist of threats to validity and a short catalogue of how various research designs neutralize those threats. Even a crude screening device to evaluate the validity of research studies, however, can go far in reducing a court's reliance upon inadequate empirical data." Monahan & Walker (1986), *supra*, at 509.

D. Subsequent to a Preliminary Finding of "Relevance" (*i.e., validity*) Under Rule 702, What Role Does 403 Play Regarding Scientific Information?

Rule 403 provides a final check on the admissibility of scientific evidence. To a large extent, Rule 403 presupposes that the relevance of the scientific information has been assessed by the judge as mandated by Rules 702 and 104. Rule 403, therefore, should not be understood as placing an affirmative obligation on scientific evidence to be valid, nor does it contain an independent standard of admissibility such as requiring "general acceptance." Rule 403 is a negative check on scientific information that, though valid, would cause so much prejudice or waste

so much time that it should be excluded. *See Huddleston*, 485 U.S. at 691 (citing Rule 403 as protection against "unduly prejudicial evidence"); *see generally* Donald N. Bersoff, *Psychologists and the Judicial System: Broader Perspectives*, 10 L. & Hum. Behav. 151, 157 (1986).

Finally, Rule 403 faithfully effectuates a central principle inherent in *Frye's* general acceptance standard. A primary purpose of *Frye* was to keep from the jury novel science that might overwhelm it. *Frye*, however, imperfectly achieved the purpose because the definition of novel scientific evidence does not necessarily correspond with expert evidence likely to excessively persuade the jury. Rule 403, operating in combination with Rule 104(a), accomplishes the job more precisely.

E. Conclusion

The matter of judges becoming effective screeners of scientific information is not merely an academic matter. There are substantial costs associated with judges continuing to fail to impose some principle on the admissibility of scientific information. The costs in court time alone to litigate cases involving shoddy science is staggering. The increasing tendency in the lower courts to adopt more stringent rules is undoubtedly a response to this phenomenon. In addition, there are enormous costs to society when defendants are forced to litigate claims that are premised upon little more than the alignment of tea-leaves. Although far from unambiguous, the Rules contain sufficiently definite principles in Article VII together with Rules 104(a) and 403 by which judges can effectively monitor the admission of scientific information.

III. SHOULD THIS COURT DISMISS THE *WRIT OF CERTIORARI* AS IMPROVIDENTLY GRANTED IN LIGHT OF THE SIGNIFICANT LEGISLATIVE ATTENTION NOW FOCUSED ON RULE 702?

One final issue must be considered regarding this Court's examination of Article VII. In 1991, the Committee on Rules of Practice and Procedure published a proposed amendment to Rule 702.[18] As this Court is likely aware, after receiving substantial public comment, the Committee decided not to recommend adoption of the proposed rule. Instead, the Committee endorsed a request to the Chief Justice that he reactivate an Advisory Committee on the Federal Rules of Evidence to revisit the issue. *See Preliminary Report: Judicial Conference Actions, September 22, 1992, Jud. Conf. of the U.S.* This recommendation has reportedly been accepted.[19]

In light of the substantial legislative attention being cast upon Article VII, the Court should consider whether the *writ of certiorari* was improvidently granted. The

[18] The proposed amendment to Rule 702 provides, in pertinent part, as follows:

> Testimony providing scientific, technical, or other specialized information, in the form of an opinion or otherwise, may be permitted only if (1) the information is reasonably reliable and will substantially assist the trier of fact to understand the evidence or to determine a fact in issue and (2) the witness is qualified as an expert by knowledge, skill, experience, training, or education to provide such testimony . . . .

Preliminary Draft of Proposed Amendments to the Fed. Rules of Civil Procedure and the Fed. Rules of Evidence, 137 F.R.D. 53, 156 (1991). The proposed amendment was designed to strengthen Rule 702 in two principal respects. First, it adds the requirement that the science be "reasonably reliable" and, second, it mandates that the evidence "substantially" assist, not merely "assist," the trier of fact. *See generally* Frederic I. Lederer, *Resolving the Frye Dilemma —A Reliability Approach*, 26 Jurimetrics 240 (1986).

[19] Telephone Interview with John Rabiej, Rules Committee Support Office, Judicial Conference of the United States (Nov. 4, 1992).

complexity of the subject and the ambiguity surrounding the construction of Rule 702 suggest that this might be an inopportune time for the Court to decide the matter. Instead, the Court might prefer to leave the matter to the Committee to study the issue extensively and construct a viable solution.

On balance, however, we do not recommend that the *writ of certiorari* be dismissed. The Committee's work is likely to take a significant amount of time to complete. In the meantime, the lower courts are likely to continue to cut different paths through the Rule 702 thicket. Given the strong interest in uniformity reflected in the passage of the Rules, continuation of the present state of affairs for any significant amount of time is not recommended.

Respectfully submitted,

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

WILLIAM DAUBERT and JOYCE DAUBERT,
Individually and as Guardians Ad Litem for
JASON DAUBERT, and ANITA DE YOUNG, Individually,
and as Guardian Ad Litem for ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

**On Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit**

BRIEF OF THE CARNEGIE COMMISSION ON SCIENCE, TECHNOLOGY, AND GOVERNMENT AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

No. 92-102

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually, and as Guardian Ad Litem for ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF THE CARNEGIE COMMISSION ON SCIENCE, TECHNOLOGY, AND GOVERNMENT AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

This brief was filed accompanied by written consent of all parties to the case.

INTEREST OF THE *AMICUS CURIAE*

This *amicus curiae* brief is submitted by the Carnegie Commission on Science, Technology, and Government ("the Commission") on the basis of work conducted by its Task Force on Science and Technology in Judicial and Regulatory Decision Making. The Commission, an independent bipartisan body, was established in 1988 by

Carnegie Corporation of New York [1] to assess, and recommend improvements in, the mechanisms by which the federal government and the states incorporate scientific and technological knowledge into policy and decision making. The Commission operates through task forces that address specific issues or organizational entities, and itself sponsors a variety of consultant studies, seminars, and workshops. The membership of the Commission is listed in the Appendix.[2]

Amicus's interest stems from its examination of judicial decision making with regard to science and technology (S&T) issues. A primary conclusion of this three-year study was that a better understanding of scientific methodology would enable the legal system to handle S&T information more effectively.

This brief is not submitted on behalf of either party. Its purpose is to explain the process by which science is conducted and to suggest that the nature of the scientific enterprise requires rejection of current tests for the admissibility of expert testimony. The Commission's approach is intentionally interdisciplinary because it believes that a broader perspective is needed in order to harmonize the interests of science and law so as to achieve improved decision making in our courts.

BACKGROUND

The Nature of the Problem

Recent developments both in law and science have conspired to bring increasingly complex scientific issues before the courts for resolution. In particular, the growth

[1] Carnegie Corporation of New York is a philanthropic foundation created by Andrew Carnegie in 1911 to promote the advancement and diffusion of knowledge and understanding.

[2] No judicial member of the Commission, its Advisory Council or the Task Force on Science and Technology in Judicial and Regulatory Decision Making has participated in any way in the decision to file a brief or in crafting the argument to present to the Court.

in environmental and toxic torts litigation has put enormous pressures on the legal system, which is simultaneously being asked to resolve questions on the cutting edge of science and to develop intricate theories of substantive law. The stress is especially great because these cases involve large numbers of persons and raise profound social, economic and public policy concerns. On the criminal side, DNA testing has brought science of the most sophisticated nature into the courtroom; the research of scientists working at the very frontiers of human knowledge has become relevant in routine criminal cases. The enactment of the Federal Rules of Evidence in 1975 has caused a further problem for the courts as judges have sought to determine the impact of the new rules on handling these new problems.

The district court needs to know its obligation when confronted with an expert who seeks to testify where the scientific evidence is in dispute. Is it the judge's sole responsibility to determine, pursuant to Fed.R.Evid. 702, whether the expert is "qualified" by education and/or experience to be a witness? If that is the only test, critics contend that "junk science" may overwhelm decision making. The "qualified" witness may be a hired gun ready to say anything, or a proponent of fringe theories. On the other hand, allowing a court to screen a "qualified" expert's opinion raises two problems: (1) Is this permissible under the Federal Rules of Evidence? and (2) How can a judge with no specialized scientific training know enough to make preliminary determinations that choose between the contentions of "qualified" experts?

Amicus believes that at this stage in the evolution of law and science, a reanalysis of problems and disaggregation of issues can provide clearer answers to these questions. We think that the Court's grant of certiorari in this case provides an opportune moment for reflection and reformulation.

The Nature of the Scientific Process

Any recasting of the judge's role in the handling of scientific evidence must take account of how science is conducted, and how science can contribute to better decision making in the courts. The essential nature of science has been described as follows:

> In broadest terms, scientists seek a systematic organization of knowledge about the universe and its parts. This knowledge is based on explanatory principles whose verifiable consequences can be tested by independent observers. Science encompasses a large body of evidence collected by repeated observations and experiments. Although its goal is to approach true explanations as closely as possible, its investigators claim no final or permanent explanatory truths. Science changes. It evolves.

National Academy of Sciences, *Science and Creationism: A View from the National Academy of Sciences* 8 (1984) (*"Science and Creationism"*).[3]

Scientists proceed by formulating hypotheses that they then test. "Rigor in the testing of hypotheses is the heart of science." *Id.* at 9. Most scientists agree that the critical task of the scientific community—in testing, refining and systemizing hypotheses—is essential to a convergence toward accurate understanding of the universe and is overlain by sociological perturbations.[4]

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[3] The Committee on Science and Creationism consisted of a distinguished group of six scientists (from four leading universities, the National Institutes of Health and the American Museum of Natural History), three partners in leading law firms, and one Harvard Law School professor, under the direction of James D. Ebert, vice president of the National Academy of Sciences.

[4] Robert Merton, *The Sociology of Science*, 267-78 (1973). Some philosophers and sociologists have gone so far as to assert that scientific "facts" are socially constructed hypotheses that contain value-laden choices. *See* Sheila Jasanoff, *What Judges Should Know About the Sociology of Science*, 32 Jurimetrics J. 345, 347 (1992) ("Observations [by scientists] achieve the status of 'facts' only if they are produced in accordance with prior agreements about the

The existing body of scientific opinion tends to be conservative, to resist dissent and surprises. This is functional, to allow a firm basis of provisionally corroborated opinion as a stepping-off place for further innovation. These opinions are not always infallible, and some dissent eventually becomes the basis for more far-reaching revisions.

The ongoing scientific endeavor must be viewed as a body of working assumptions, of contingent and sometimes competing scientific claims, likely to be refined even when the core insights are validated with the passage of time and under the glare of pluralistic criticism.[5]

In light of this indeterminacy, how can a judicial system make use of a scientific "fact"? The dynamic nature of the scientific process suggests the impossibility of formulating any legal test of admissibility that requires a court to evaluate the validity of an evolving hypothesis or to choose between competing hypotheses. *Amicus* suggests instead that courts should focus on determining whether the expert engaged in recognized forms of scientific practice in reaching his or her conclusion.

The scientific community uses a variety of markers in evaluating scientific practice—both general markers that extend across fields and specific markers that pertain to a particular discipline. Although appropriate scientific practices cannot be reduced to a single, definitive list, it is possible to suggest the kinds of factors that enter into the analysis. The degree of the scientific claim's accept-

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rightness of particular theories, experimental methods, instrumentation techniques, validation procedures, review processes, and the like. These agreements, in turn, are socially derived through continual negotiation and renegotiation among relevant bodies of scientists.").

[5] Thomas S. Kuhn, *The Structure of Scientific Revolutions* (1970) (suggests that scientific communities adopt "paradigms" that operate as the accepted "disciplinary matrix" until a new paradigm emerges; *id.* at 182; a paradigm "like an accepted judicial decision in the common law . . . is an object for further articulation and specification under new or more stringent conditions." *Id.* at 23.)

ance within a scientific field or discipline reflects the degree to which it has been produced in conformity with the scientific process. Another relevant criterion is the capacity of the claim to withstand criticism, as exemplified by whether a tradition of peer review or other mode of institutionalized self-criticism exists within the field to which the expert belongs. Of central importance is whether the expert adhered to generally recognized forms of scientific inquiry. While different fields utilize somewhat different standards, making it impossible to arrive at a single definition about the nature of scientific practice, and some gray areas of disagreement may exist as to whether the methodology used in testing a particular scientific claim was adequate, some boundary exists beyond which it is no longer possible to consider the claim as having been developed in accordance with recognized scientific practice.

Conventions regarding scientific methodology are analogous to the evidentiary rules that developed in response to our inability to ascertain the objective "truth" of a past historical event. Evidentiary rules seek to curb potential errors in legal fact-finding even though we have little or no empirical evidence that they actually do. The scientific conventions on how research should be done represent the expertise of the scientific community on the best way to ensure that scientific hypotheses conform with a possible state of affairs.

SUMMARY OF ARGUMENT

The core issue in this case is how the federal courts should think about scientific evidence. In the instant case this complex problem is presented in terms of admissibility, raising the issues of whether, when, and to what extent a federal judge may scrutinize an expert's opinion to determine whether it is admissible pursuant to the Federal Rules of Evidence.

This brief takes a somewhat broader view. Because the expertise of the *amicus* centers on the interrelationship between science and law, we discuss more than

admissibility. This brief proposes an integrated approach to scientific evidence that will acknowledge and respect both the special expertise of science and the judge's responsibility to declare the law. It is an attempt to render unto science the concerns of science, and to the law that which lies in the law's domain.

We look first at the judge's task in ruling on the admissibility of evidence, and propose a new set of criteria geared to the process by which scientific hypotheses are developed—criteria that require the court to consider whether the scientific claim on which the expert's opinion rests is the product of a recognized form of scientific inquiry. An opinion that purports to answer a scientific question without having engaged in an appropriate scientific inquiry is incapable of providing a systematic explanation that satisfies our demand for rational proof.

Because judges are increasingly being asked to consider scientific thinking in the context of rulings on the sufficiency of evidence, however, we take the liberty of also exploring the very different questions about scientific evidence that a court may have to examine in that context. We think such an examination completes the picture of the judge's responsibility vis-à-vis scientific evidence, sheds light on the admissibility problem, and helps delineate the respective spheres of scientist and judge.

We strongly urge this Court to go beyond the simplistic "general acceptance" test derived from *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). "General acceptance" is an inadequate vehicle for thinking about science in the courtroom. It fails to provide federal judges with sufficient guidance on how to analyze complex scientific issues because its formula is too vague and misleading, and is incompatible with the essence of the scientific endeavor. The unresponsiveness of "general acceptance" to the scientific process leads to an unprincipled test that taken literally rejects valuable insights that bear all the hallmarks of acceptable science, but provides no guidance on how to distinguish the product of marginal or insupportable fringe activities.

We also argue that making peer review a sole condition for the admissibility of all scientific evidence is ill-advised. Imposition of such a requirement does not reflect the realities of either litigation or the role of science in litigation.

ARGUMENT

I. WHEN RULING ON WHETHER AN EXPERT'S OPINION BASED ON SCIENTIFIC EVIDENCE IS ADMISSIBLE, A COURT SHOULD DETERMINE IF THE UNDERLYING SCIENTIFIC CLAIM WAS THE PRODUCT OF A RECOGNIZED FORM OF SCIENTIFIC INQUIRY.

An expert opinion that is purportedly based on scientific observation is of value in resolving a controverted issue only if it embodies a scientifically plausible mode of reasoning. Separating valid from invalid hypotheses requires that the judge understand science as a process of producing claims about the actual world. It does not require that a judge understand or undertake an extensive examination of the hypotheses being put forth.

A. The Two Current Modes of Analysis

1. *The* Frye *test.*

Prior to the enactment of the Federal Rules of Evidence many federal courts purported to follow the so-called "general acceptance" test that had its genesis in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).[6]

[6] In *Frye*, the court had stated:

> Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.

Id. at 1014.

Since the enactment of the Federal Rules, some courts have continued to give allegiance to *Frye*, and one of the questions before this Court is whether *Frye* has survived the advent of the Federal Rules. *Amicus* requests the Court to discard *Frye*, not because a federal court does not have the power to make threshold determinations with regard to the admissibility of scientific evidence,[7] but because "general acceptance" is an ineffective test that misconceives the nature of the scientific enterprise. It assumes that there is much more definiteness in science than actually exists, and that this precision takes the form of widely held beliefs about reality that can readily be found. *See* Sheila Jasanoff, *What Judges Should Know About the Sociology of Science*, 32 Jurimetrics J. 345 (1992). In fact, scientific claims remain provisional and continue to be challenged until incentives for investigating the problem disappear.[8]

2. *The* Downing *test.*

In *United States v. Downing*, 753 F.2d 1224 (3d Cir. 1985), the Third Circuit formulated an alternative to the "general acceptance" test. The *Downing* test centers

[7] *See United States v. Downing*, 753 F.2d 1224, 1235 (3d Cir. 1985) ("[W]e can assume that the drafters of the Federal Rules of Evidence were aware that the *Frye* test was a judicial creation, and we find nothing in the language of the rules to suggest a disapproval of such interstitial judicial rulemaking. Therefore, although the codification of the rules of evidence may counsel in favor of a re-examination of the general acceptance standard, on balance we conclude that the Federal Rules of Evidence neither incorporate nor repudiate it.").

[8] *Science and Creationism*, *supra* p. 4 at 10. ("Scientific theories . . . allow us to anticipate yet unknown phenomena and thus to focus research on more narrowly defined areas. If the results of testing agree with predictions from the theory, the theory is provisionally corroborated. If not, it is proved false and must be either abandoned or modified to account for the inconsistency.

"Scientific theories, therefore, are accepted only provisionally. It is always possible that a theory that has withstood previous testing may eventually be disproved.").

on two factors: "(1) the reliability of the scientific principles upon which the expert testimony rests . . . and (2) the likelihood that introduction of the testimony may in some way overwhelm or mislead the jury." *Id.* at 1226. Although some of the considerations that the *Downing* court identified as relevant to an assessment of reliability are factors that the criteria proposed below would consider,[9] the thrust of our proposal is somewhat different, and in our view more reflective of scientific practices.

Our principal difficulty with the *Downing* approach is one of emphasis. Its stress on reliability suggests that a federal judge in ruling on admissibility should evaluate the *content* of the scientific evidence. The wording implies that an unscientifically trained judge will be able to determine the true state of scientific knowledge. *Id.* at 1239, n.19 (suggesting that a district court may appoint a Fed. R. Evid. 706 expert if the court has doubts that the foundational evidence "reflects the true state of scientific knowledge and opinion about it"). The *Downing* approach fails to accord sufficient deference to science to produce valuable results when a process consonant with scientific methods is employed. We suggest therefore that it is the *process* by which the theory was generated or tested that needs to be examined.

B. Rationale for Criteria Proposed and the Power of the Court

We suggest that when a court is ruling on the admissibility of expert testimony grounded in science it

[9] The *Downing* court suggested that the following eight factors might bear on scientific accuracy: (1) the degree of acceptance within the scientific community, (2) the novelty of the technique, (3) the existence of specialized literature dealing with the technique, (4) the qualifications and professional stature of the witness, (5) the non-judicial uses to which the scientific technique is put, (6) the frequency with which a technique leads to erroneous results, (7) the type of error generated by a technique, and (8) any expert testimony that has been offered in earlier cases to support or dispute the merits of a particular scientific procedure.

should determine whether scientific claims[10] have been developed within the bounds of a recognizable form of scientific inquiry. In order to make this inquiry, the court should consider the following criteria:

1. Is the claim being put forth testable?

2. Has the claim been empirically tested?

3. Has the testing been carried out according to a scientific methodology?[11]

The opinion should be rejected if the answer to any of these questions is in the negative. These questions seek to answer whether the opinion lies beyond the boundary of a recognized scientific inquiry. If it does, then the opinion cannot "assist" the trier of fact as required by Rule 702 of the Federal Rules of Evidence because it does not conform to the characteristics of "scientific

[10] We use the word "claim" rather than theory because we recognize that an expert's opinion may be admissible even in the absence of an explanatory theory. For instance, an expert could rely on an epidemiological study showing a significant association between exposure to a substance and a disease without positing a theory on precisely how the substance causes the disease to develop.

[11] We recognize that there are two additional questions that a court may have to decide:

(1) whether the theory fits established facts in the case; if it does not, it is not relevant according to Fed. R. Evid. 401. *See, e.g., Bernhardt v. Richardson-Merrell, Inc.*, 892 F.2d 440 (5th Cir. 1990) (drug exposure occurred after that point in pregnancy at which particular birth defect could have occurred); *Novak v. United States*, 865 F.2d 718, 723-24 (6th Cir. 1989) (even if epidemiological evidence supported expert's contention of an increased incidence of persons contracting a particular disease within fifteen days of a swine flu vaccination, evidence showed that decedent's symptoms commenced considerably after fifteen days).

(2) whether the expert is qualified. An expert may be unqualified because of insufficient expertise regardless of whether the scientific claim the expert wishes to put forth would meet the suggested criteria.

Since these questions do not relate to the test being proposed, we do not discuss them further.

knowledge." In other words, absent these characteristics the court should reject the opinion as not resting upon a foundation that would enable a reasonable person to draw reasonable inferences.

These questions are preliminary questions about the admissibility of evidence that must be determined by a court pursuant to Rule 104(a) of the Federal Rules of Evidence using a preponderance of the evidence standard. These questions about the characteristics of science are of a technical nature. They are the kinds of questions that historically have been allocated to a court rather than a jury. *See* John Maguire and Charles Epstein, *Preliminary Questions of Fact in Determining the Admissibility of Evidence*, 40 Harv. L. Rev. 392, 393-94 (1927) (among the reasons advanced for allocating a preliminary issue to a judge are: (1) simplifying issues for a jury; (2) improving the consistency or predictability of results; (3) sharpening issues on appeal; and (4) increasing the speed of trial).

The test we propose should lead to more efficient litigation because technical issues relating to the methodology of the study may be dispositive. Furthermore, the foundational requirement would force experts to divulge early in the litigation process the information needed to determine whether the underlying hypothesis was developed in conformity with scientific criteria. This test eases a court's task because it requires courts to make the kinds of determinations they typically make instead of asking them to evaluate the status of scientific theories or to assess their contents, questions far removed from the expertise of judges. Both the *Frye* and *Downing* tests suggest to judges that they need to comprehend complex principles of science with which they are unfamiliar and which they can ill afford the time to master.

C. The Hallmarks of a Scientific Mode of Inquiry

1. *Is the Claim Testable?*

Courts have rarely sought to identify the line of demarcation between science and non-science, although all

judges would undoubtedly refuse to admit certain evidence—such as predictions based on astrology—as capable of proving a fact in issue. Philosophers of science view science as an empirical endeavor with at least two essential characteristics. In order for a theory on which an expert relies to be deemed "scientific" (1) it must set forth a hypothesis that is capable of being proven false through observation or experiment,[12] and (2) the data produced through this testing must be capable of replication.[13] *See* Karl R. Popper, *The Logic of Scientific Discovery* 46 (1959). We suggest that this framework be employed in determining whether a particular claim is capable of affording a scientific explanation. Thus, opinions based on claims that are not capable of being tested should not be admitted into evidence.[14] Claims that are

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[12] Karl R. Popper, *The Logic of Scientific Discovery* 40-41 (1959) ("I shall not require of a scientific system that it shall be capable of being singled out, once and for all, in a positive sense; but I shall require that its logical form shall be such that it can be singled out, by means of empirical tests, in a negative sense: *it must be possible for an empirical scientific system to be refuted by experience.*") (emphasis in original); Lee Loevinger, *Standards of Proof in Science and Law*, 32 Jurimetrics J. 323, 327 (1992) ("Indeed, the distinguishing characteristic of a scientific hypothesis, as differentiated from one that is merely logical or metaphysical, is that it is capable of being falsified. An hypothesis that is tested and not falsified is corroborated, but not proved.").

[13] Panel on Scientific Responsibility and the Conduct of Research, Committee on Science, Engineering, and Public Policy, National Academy of Sciences, National Academy of Engineering, Institute of Medicine, I *Responsible Science: Ensuring the Integrity of the Research Process* 59 (1992) ("In accordance with established principles of science, scientists have the responsibility to replicate and reconfirm their results as a normal part of the research process. The cycles of theoretical and methodological formulation, testing, and reevaluation, both within and between laboratories, produce an ongoing process of revision and refinement that corrects errors and strengthens the fabric of research.").

[14] *Cf. United States v. Baller*, 519 F.2d 463, 466 (4th Cir.), *cert. denied*, 423 U.S. 1019 (1975) ("[T]here must be a demonstrable, objective procedure for reaching the opinion and qualified persons who can either duplicate the result or criticize the means by which

supported by data that cannot be replicated should likewise be rejected.[15]

2. *Has the Claim Been Tested?*

Even if the expert's underlying hypothesis is capable of being tested, the question remains whether the claim being asserted in the courtroom has in fact been subjected to an empirical scrutiny making it the product of a scientific inquiry.[16] Peer review in connection with a research grant or publication, or general acceptance in the scientific community as evidenced by periodical literature, should constitute presumptive proof that testing of the hypothesis has taken place.[17]

The lack of peer review or the failure of a theory or claim to have achieved a consensus in the scientific community does not, however, guarantee an absence of testing. It does mean that the court will have to look for other indicators of empirical review if the expert's opinion is challenged.

The opinion should be rejected if the theory or claim has not been tested and if proof of the theory or claim is critical to the conclusion that the expert seeks to draw.

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it was reached, drawing their own conclusions from the underlying facts.").

[15] *See, e.g., DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 791 F. Supp. 1042, 1047-49 (D.N.J. 1992) (neither plaintiff's nor defendant's experts could replicate recalculations done by plaintiff's witness who himself could not explain how he arrived at certain numbers).

[16] *Science and Creationism*, *supra* p. 4 at 9 ("The task of systemizing and extending the understanding of the universe is advanced by eliminating disproved ideas and by formulating new tests of others until one emerges as the most probable explanation for any given observed phenomenon. This is called the scientific method.").

[17] The word "presumptive" is used because scientific misconduct sometimes occurs that is undetected by the peer review system. *See* Daryl E. Chubin & Edward J. Hackett, *Peerless Science* 125-53 (1990) (to counter the presumptive admissibility of a peer-reviewed study, the opponent would have to make a preliminary showing that such misconduct occurred); Sheila Jasanoff, *The Fifth Branch* 71-76 (1990).

For instance, an expert witness should not be allowed to conclude that substance X caused disease Y if he is relying on nothing more than a temporal association between the exposure and the injury. Without some empirical validation of the expert's hypothesis, the testimony amounts to nothing more than describing two events that are sequentially, but not necessarily causally, connected. *See, e.g., Porter v. Whitehall Lab., Inc.*, 791 F. Supp. 1335, 1344-45 (S.D. Ind. 1992); *Boyles v. American Cyanamid Co.*, 796 F. Supp. 704, 709 (E.D.N.Y. 1992) ("Each expert's methodology amounts to little more than a giant leap of faith from the alleged coincidence of the chemical exposure and [the plaintiff's] experiencing of certain symptoms. The exclusion of both experts herein is compelled by the nonexistence of any medical or scientific study which supports their conclusion.").

The lack of empirical testing may not be apparent until the evidence is challenged.[18] In a Maine case involving DNA testing, for instance, it emerged that the commercial laboratory analyzing the DNA had declared a match even though the two samples being compared had not quite matched because of bandshifting. The laboratory's experts simply corrected all of the bands in the displaced sample by a given percentage despite the lack of research showing the accuracy of such corrections.[19] *Jasanoff*, *supra* note 4 at 350-51 (discussing *Maine v. McLeod*, CR-89-62 (Cumberland County, Me., July 18, 1989)). *Cf.* NRC Report, *supra* note 19 at 76 (although the uniqueness of DNA in all persons other than identical

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[18] Part of the problem may be that the *Frye* formula, when it speaks of "the particular field in which it [the theory] belongs," obscures the possibility that empirical evidence from more than one field may be required in order to reach the conclusion that the expert wishes to state.

[19] *See also* National Research Council, *DNA Technology in Forensic Science* 61 (1992) ("NRC Report") (suggesting that because of the present inadequacy of research on the nature of bandshifting and on the various techniques that laboratories use to make corrections, samples should be declared "inconclusive" if they show bandshifting).

twins has been so firmly established that it ought to be subject to judicial notice, the DNA typing systems in use examine only a few sites of DNA variation; until further research resolves questions about the adequacy of population databases on which the frequencies of specific DNA typing patterns are based, judges should exercise caution in permiting an expert to characterize the probability of a match of two DNA samples in mathematical terms.).

3. *Has the Testing Been Carried out According to a Scientific Methodology?*

Peer review and/or recognition in the scientific community are presumptive guarantees not only that the theory was tested, but also that the testing was methodologically sound. In the absence of these factors, a court may have to rely on other factors to determine if the methodology producing the claim satisfied scientific standards. The court may, for instance, have to examine the study design,[20] data collection[21] or error rate[22] to

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[20] *See Viterbo v. Dow Chemical Co.*, 826 F.2d 420, 423 (5th Cir. 1987) (plaintiff claimed that his depression was caused by exposure to defendant's pesticide; plaintiff's expert ignored test result that revealed high level of another chemical in plaintiff's blood that can cause depression on the ground that plaintiff had denied having contact with that chemical; appellate court affirmed district court which had granted summary judgment on the ground that evidence was excludible under Fed. R. Evid. 703).

[21] *See, e.g., DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 791 F. Supp. 1042 (D.N.J. 1992) (errors in entering data, relying on superseded data, and data that experts in the field would not use). The court analyzed these problems under Rule 703 of the Federal Rules of Evidence. Restructuring these problems as methodological problems means that there is no need to consider whether Rule 703 operates as an independent basis for rejecting evidence, or is only intended to operate as a hearsay exception. Compare the *per curiam* and concurring opinions in *Christophersen v. Allied Signal Corp.*, 939 F.2d 1106, 1114, 1118 (5th Cir. 1991) (*per curiam*), *cert. denied*, 1126 S.Ct. 1280 (1992).

[22] *In re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829, 857 (3d Cir. 1990), *cert. denied*, 111 S.Ct. 1584 (1991) (*"In re Paoli"*)

determine whether the methodology used was so skewed as to justify exclusion. The question is not whether the judge agrees with the results of the study or the scientific assumptions on which the study is based. Rather the court must decide whether the study was set up and carried out in a manner that conforms to standards in the scientific community.

These factors are interrelated; a slight modification of a well-established theory may require less in the way of scientific investigation than a brand new hypothesis. These factors do not have a quantitative threshold. We are not proposing that studies must be designed in a certain way, or contain a fixed number of subjects, in order for a court to allow an expert to state an opinion derived from these studies. We do suggest, however, that after considering these factors, and perhaps others, a court may conclude that the scientific claim being put forward has not been examined in a manner consonant with the requirements of a recognized scientific inquiry.

The main impact of this test would be two-fold: (1) judges and litigants would better understand the need to produce this information early in the litigation, and (2) judges would better understand that the limited focus of their inquiry—to determine whether appropriate testing occurred—is equivalent to other foundational inquiries they frequently make. *See, e.g., Manual for Complex Litigation*, Second, § 21.484 (providing that the admissibility of estimates obtained by sampling "will depend upon the procedures employed in selecting the sample and in obtaining information from or about the

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(there would be grounds for exclusion "if there were evidence in this record that meta-analysis is inaccurate as a mode of analysis—that the concept of combining raw data from different independent studies and re-analyzing it in total does not render accurate results."); *United States v. Smith*, 869 F.2d 348, 353-54 (7th Cir. 1989) (examination of error rates and types of errors with regard to voiceprint evidence). *See also* Michael Saks & Jonathan Koehler, *What DNA "Fingerprinting" Can Teach the Law About the Rest of Science*, 13 Cardozo L. Rev. 361, 368 (1991).

sample. The proponent of such evidence has the burden of establishing conformity with generally recognized statistical standards, a task that will ordinarily involve expert testimony."); *Pittsburgh Press Club v. United States*, 579 F.2d 751 (3d Cir. 1978) (setting out criteria for sampling).

Ascertaining if an appropriate scientific methodology was used in testing a theory does not require the court to undertake the far more difficult task of comprehending and assessing the substance of the theory. Furthermore, although the dissonance between "general acceptance" and the provisional nature of scientific claims makes "general acceptance" an inapt guide for the admissibility of evidence, general agreement on the methodological standards for a particular discipline is feasible. *See, e.g.*, Technical Working Group on DNA Analysis Methods, *Guidelines for a quality assurance program for DNA restriction fragment length polymorphism analysis*, Crime Lab Dig. 16 (2): 40-95 (1989) (guidelines developed by the FBI, the Royal Canadian Police, state forensic laboratories and commercial laboratories to deal with issues such as documentation, validation of procedures, proficiency testing, handling and labeling of samples and laboratory contamination); Devra L. Davis, Barbara Mandula and John Van Ryzubm, *Assessing the Power and Quality of Epidemiologic Studies of Asbestos-Exposed Populations*, 1 Toxicology & Indus. Health 93 (1985) (reporting on Ontario Royal Commission report and a National Research Council report, both of which evaluated asbestos studies in terms of methodologic factors) (epidemiological studies); Association of the Bar of the City of New York, *Recommendations on Pretrial Proceedings in Cases with Voluminous Data, reprinted in The Evolving Role of Statistical Assessments in the Courts* 245-54 (Fienberg ed. 1988) (standards for statistical experts).

Furthermore, the court may be able to get neutral assistance to deal with this issue. Under the *Frye* test or the *Downing* test, courts may be loath to turn to a

court-appointed expert because any expert who knows enough to comment on the particular claim's position in the scientific community, or its reliability, may well be so closely involved with the controverted substantive theory that the court fears bias. Finding an expert to advise the court about methodology is considerably easier; persons who have no special knowledge about the particular controverted substantive issue can be knowledgeable about a field's methodological requirements. *See Renaud v. Martin Marietta Corp.*, 749 F. Supp. 1545, 1552 (D. Colo. 1990), *aff'd*, 972 F.2d 304, 307-08 (10th Cir. 1992) (court granted summary judgment for defendants in case alleging that plaintiffs' cancers and birth injuries were caused by toxic wastes dumped in water after court-appointed geologist advised court that it was an "unsound scientific practice" to base all conclusions about the continuous release of contaminants over an 11-year period on one sample of water).

D. The Operation of the Proposed Test: Foundational and Procedural Requirements

According to the test proposed, the foundational information needed to determine if the theory had been tested in accordance with scientific methods would have to be disclosed in the expert's report during discovery [23]

[23] Although the current Federal Rules of Civil Procedure do not require disclosure of experts' reports, or authorize depositions absent court order, in practice, parties frequently stipulate to exchange experts' reports and to depose all experts. Day, *Expert Discovery in the Eighth Circuit: An Empirical Study*, 122 F.R.D. 35, 50, 57 (1988) (88% of attorneys responding reported depositions by stipulation and exchange of information). Under proposed amendments to the Rules of Civil Procedure, these provisions would become mandatory. *See* Standing Committee on Rules of Practice and Procedure of the Judicial Conference of the United States, *Proposed Amendments to the Federal Rules of Civil Procedure* (Sept. 1992) (requires mandatory disclosure from experts of "a complete statement of all opinions to be expressed and the basis and reasons therefor; the data or other information considered by the witness in forming the opinion; any exhibits to be used as a summary of or support for the opinions . . .").

or at the final pretrial conference.[24] If prior to trial a party failed to show that an expert listed as a trial witness had relied on a properly tested theory, then the opponent could move *in limine* to exclude that expert's testimony.[25]

A court need not conduct a hearing unless (1) the movant adequately showed that it cannot be ascertained from the reports whether the expert's theory was tested, or tested appropriately, and (2) the expert failed to supply the missing information. A refusal to produce needed foundational material should lead to preclusion of the expert. In cases where there is a genuine dispute about adequate testing, the court may need to hold a hearing.

Although hearings obviously consume scarce judicial time, they may in the long run lead to shorter and less expensive proceedings. They would avoid results such as the enormous investment of appellate time in *Christophersen v. Allied Signal Corp.*, 902 F.2d 362 (5th Cir. 1990), *rev'd en banc*, 939 F.2d 1106 (5th Cir. 1991), *cert. denied*, 112 S.Ct. 1280 (1992),[26] in which the central

[24] A court has adequate power to require experts to produce reports in connection with the final pretrial conference. *See* Fed. R. Civ. Pro. 16(c)(11) (providing that the court may take action regarding "such other matters as may aid in the disposition of the action") and (d) (providing that at a final pretrial conference, the participants "shall formulate a plan for trial, including a program for facilitating the admission of evidence.").

[25] This requirement is not inconsistent with Fed. R. Evid. 705 which provides that an expert may *testify* "without prior disclosure of the underlying facts or data." Rule 705 is a rule that applies at trial only; it has no bearing on threshold requirements that have to be satisfied before the expert will be allowed to testify.

[26] In *Christophersen*, affidavit of the plaintiff's expert stated that decedent's death from a rare form of colon cancer was due to exposure to nickel and cadmium fumes at his place of work; expert conceded the absence of epidemiological, animal or in vitro studies investigating this association, but stated that nickel and cadmium had been implicated in small-cell carcinoma of the lungs, that the cells in decedent's colon cancer were likewise small, and that "[b]ased on what's known about the biochemical nature of small-cell" carcinoma, one could conclude that small-cell carcinoma throughout the body had a similar pathogenesis. *Christophersen* at 1115. The affidavit of the defendant's expert alleged that "[t]hese tumors in fact have to my knowledge never have been shown to have a common causation or share a proven common origin." 902 F.2d 362, 366 (5th Cir. 1990). The district court granted summary judgment for defendant on the basis of these affidavits without conducting a hearing. The four defense affiants were never deposed. 939 F.2d at 1122.

dispute, according to the test proposed by *amicus*—has plaintiff's expert's claim been empirically tested or is it merely a hunch?—was never explored in a procedural posture that allowed the development of an adequate record.[27]

II. WHEN RULING ON THE SUFFICIENCY OF SCIENTIFIC EVIDENCE, A COURT MUST EVALUATE THE EVIDENCE IN LIGHT OF A LEGAL STANDARD OF PROOF.

A. The Legal Standard for Sufficiency

When a defendant challenges scientific evidence as insufficient, whether before trial, at trial, or after trial, the question for the court remains the same. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250-52 (1986). May the court conclude as a matter of law that the evidence "is so one-sided that one party must prevail?" *Id.* at 251-52. If the answer is yes, then the court must dismiss the case without submission to the jury. Questions of sufficiency will arise when the defendant claims that the scientific evidence underlying plaintiff's claim is such that no reasonable juror could find for the plaintiff.

[27] *In re Paoli, supra* note 22 at 855 (reversing grant of summary judgment on affidavits; "At least some process should have been devised to afford plaintiffs a surrogate for that trial scenario where the equivalent evidentiary exclusion and adverse judgment might occur.").

B. Relating the Legal Standard to Scientific Proof

Ordinarily, if plaintiff and defendant have presented conflicting hypotheses that are the product of an appropriate scientific inquiry, the jury will have to resolve the controverted issues. If the defendant challenges the sufficiency of the plaintiff's evidence, however, the court will first have to decide whether an issue for the jury exists.

Whether evidence is sufficient is a matter of law, not science. In scientific hypothesis testing, the hypothesis being investigated (the "alternative" hypothesis) is accepted only if the data obtained would be quite unlikely to result if the alternative hypothesis were not true. When scientists reject the "null" hypothesis,[28] they are not making a statement of an established "truth."[29] They are making a probabilistic statement given the present state of knowledge. Determining the legal consequences that flow from this imperfect state of knowledge lies beyond the domain of science.[30]

It is a court that must decide whether the degree of scientific uncertainty is such that the plaintiff has failed to introduce sufficient probative evidence to meet its bur-

[28] The state of events in the absence of the alternative hypothesis is usually referred to as the "null" hypothesis.

[29] *Cf.* Office of Science and Technology Policy (OSTP), *Chemical Carcinogens: A Review of the Science and Its Associated Principles*, 50 Fed. Register 10371-10442 (1985) (Principle 19: "A high-quality negative epidemiological study, while useful, cannot prove the absence of an association between chemical exposure and human cancer.").

[30] Institute for Health Policy Analysis of Georgetown Medical Center, *Conference on Causation and Financial Compensation* 18 (1986) ("A conscientious scientist will weigh the available data and reach an assessment of its strength, but science cannot tell the scientists at what point the data are strong enough to warrant an award of compensation. One may or may not agree with the legal concepts and may propose alternatives, but one cannot look to science for an absolute *decisionmaking* standard because none exists.") (emphasis in original).

den of proof.[31] When the plaintiff is seeking compensation for injuries allegedly suffered because of exposure to a toxic substance, for instance, it is the judge and not a scientist who must bear ultimate responsibility for determining whether the scientific evidence satisfies the legal standard of proof. In ruling on sufficiency, the court, therefore, properly evaluates the present state of available scientific knowledge. Since determinations about the sufficiency of scientific evidence entail policy concerns, the court will also have to consider the underlying objectives of science and the law in order to ascertain the extent to which scientists' conclusions have relevance for the legal system. An example of the kind of question courts must answer is discussed below.

Animal Studies and Epidemiological Evidence. Studies showing that a particular substance may cause harm in animals are routinely used in risk assessment. Ordinarily, the goal of risk assessment is not to prove causation, but rather to characterize the nature and possibility of harm and its consequences. When animal studies are introduced in litigation by plaintiffs to prove causation, two assumptions must be made in order for the evidence to be probative: (1) that if the substance was toxic in animals it would also be toxic in humans; and (2) that extrapolation is possible from the higher and more intense level used in the study to the lower level at which the plaintiff was actually exposed.

If a plaintiff relies solely on animal studies, how should a court rule on sufficiency? Can it say that jurors may not be permitted to decide such a case because the extrapolations required to make these studies relevant to humans mean that they are insufficient to prove causa-

[31] Lee Loevinger, *On Logic and Sociology*, 32 Jurimetrics J. 527, 530 (1992) ("there is no logically rigorous definition of what a statement of probability means with reference to an individual instance").

tion?[32] Or should the court allow the case to go to the jury since a high correlation does in general exist with regard to human and animal reactions? Or should the court approach the problem by focusing on the particular animal study in question and determining whether it has a statistical significance and biologic plausibility sufficient to satisfy the plaintiff's burden of proof.[33]

Although the court's analysis will be informed by the available science, the judge's decision whether this available evidence is "so one-sided" that plaintiff must lose is ultimately a policy issue that an appellate court may have to resolve. Whether a plaintiff should be precluded by a judge from receiving compensation if such evidence is all that is available, or whether plaintiffs should be given the opportunity of having a jury decide the causation issue is in part determined by judicial views on the social policies underlying products liability law.

Most of the decided cases involving animal studies have, however, arisen in a different context. The question has not been whether plaintiff has made a prima facie case solely on the basis of animal studies, but rather whether plaintiff's animal study evidence is sufficient when the defendant's epidemiological proof does not show

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[32] *Cf. In re Paoli, supra* note 22 at 853 n.27 (suggesting that the trial court "may have meant to exclude the animal studies as irrelevant under Rule 402 because, even if they showed correlation between PCBs and animal disease, they were not probative of a connection between PCB exposure and human disease.").

[33] *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1359 (6th Cir. 1992) (The court left open the possibility that "there may be other animal experiments which . . . because of the extreme toxicity of the substance tested, would permit a reasonable jury to find that it is more probable than not that the substance causes a similar harm to humans."). Because animal studies are routinely used in the risk assessment of foods, drugs, and other substances it is theoretically possible, but unlikely, that such extreme toxicity will arise in connection with a tort claim.

any effect on humans.[34] In resolving these cases on sufficiency grounds, many courts have nevertheless cited evidentiary rules dealing with admissibility.[35] We suggest that the Federal Rules of Evidence do not apply at this point in the analysis. The court must decide whether the availability of epidemiological proof relating to humans leads to the conclusion that the contrary studies about animals' reactions have been shown not to be probative.[36] If the court so decides, and consequently finds that plaintiffs have failed to meet their burden of proof, it is creating a rule of law. It is saying that once sufficient epidemiological evidence exists a plaintiff may no longer reach the jury solely on the basis of animal studies.[37]

III. A THEORY UNDERLYING AN EXPERT'S OPINION NEED NOT HAVE BEEN SUBJECTED TO PEER REVIEW IN ORDER TO BE ADMISSIBLE.

The Ninth Circuit's opinion below strongly suggests that scientific studies prepared in anticipation of litigation must be rejected if they have not been subject to peer review. *Daubert v. Merrell Dow Pharmaceuticals,*

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[34] *See, e.g., Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 313-14, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990) ("Brock v. Merrell Dow"); *In re Agent Orange Product Liability Litigation*, 611 F. Supp. 1267, 1273 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988).

[35] *See, e.g., Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989) (case arose in procedural posture of a judgment n.o.v. granted by the trial court, but the court seems to be relying on Fed. R. Evid. 703).

[36] The likelihood that an epidemiological study would show the defect in question will have to be considered.

[37] *See, e.g., Brock v. Merrell Dow, supra* note 34 at 312. But "sufficient" does not mean a single negative epidemiological study. In fact, epidemiology offers standardized expressions of the size of effect that might be present yet not be detected in a study of a particular size or power.

Inc., 951 F.2d 1128, 1131 (9th Cir. 1991), *cert. granted*, 61 U.S.L.W. 3284 (1992). Although we agree that when a study has been peer-reviewed, it has presumptively been conducted in accordance with the dictates of scientific methodology, we do not think that an absence of peer review proves that the study lacks these characteristics.[38]

A. Peer Review as a Sole Condition Is Incompatible with the Realities of Litigation.

A requirement that all studies must be peer-reviewed before they can be relied upon by an expert witness presupposes a view of litigation and science at odds with reality. It assumes that scientific answers exist that are waiting to be summoned when a legal issue appears that hinges on scientific proof. In actuality, recent developments in both the criminal [39] and civil [40] spheres indicate quite clearly that often the studies that become relevant in determining a legal issue are initiated in reaction to the litigation process.

Insisting that parties' responses to this ongoing process be limited to studies that have been peer-reviewed is

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[38] Other courts have declined to exclude expert testimony solely because it relies on studies that have not been subjected to peer review. *See In re Paoli*, *supra* n.22; *Brock v. Merrell Dow*, *supra* note 34 at 313.

[39] A comparison of a 1990 article on DNA testing, Janet Hoeffel, *The Dark Side of DNA Profiling: Unreliable Scientific Evidence Meets the Criminal Defendant*, 42 Stan. L. Rev. 465 (1990) (raises numerous as yet uninvestigated and unresolved issues) with the NRC Report, *supra* note 19 indicates how scientific research evolved, and is continuing to evolve, in reaction to forensic pressures.

[40] *See* Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hast. L.J. 301, 331-48 (1992) (examines Bendectin research over the life cycle of the Bendectin litigation and concludes that "[t]here was a substantial mobilization of resources devoted to the study of Bendectin, much of it apparently in response to the litigation and concomitant political pressure." *Id.* at 347.).

unresponsive to the constraints imposed by litigation. How can lawyers prepare if the competence of their experts to testify is contingent, not on the scientific nature of their work, but on whether it will have been accepted for publication by the time a motion for summary judgment is made? Suppose the editorial review of the paper is in the process of negotiation—must the legal process halt? [41]

B. Peer Review as a Sole Condition Is Incompatible with the Role of Science in Litigation.

Peer review is not an objective, universally accepted set of procedures but rather a process that reflects the social processes and social conflicts that underlie scientific claims. The peer review process operates in part to clarify and to improve work presented for publication, and in part to make particular scientific research communities relatively immune to criticism from outsiders. Consequently, a person who is advocating a view at odds with the currently received wisdom may encounter difficulties in having his or her work published.

The real purpose of peer review, however, is not getting the article into the journal, but the *fact* of its publication—which makes the claims accessible to the skepticism of the larger scientific community. This important and constructive gatekeeping function of peer review is the reason we endorse its use as a factor indicating proper scientific practices.

The entanglement of peer review with the adversarial process, however, remains a challenge. If peer review is not mandatory, a lawyer's natural inclination will be to

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[41] *See* Daryl E. Chubin & Edward J. Hackett, *Peerless Science* 88 (1990) ("Today peer review has the character of an extended trilateral negotiation among authors, editors, and reviewers. Papers are rarely accepted at first sight, but instead undergo at least one and not uncommonly as many as five rounds of revision and publication.").

advise any scientist hired as an expert not to submit for publication work commissioned in anticipation of litigation. The lawyer will be afraid that any rejection, modification, inquiry or criticism by a journal or reader will be used by an opponent in litigation to discredit the work. Were peer review to become mandatory, on the other hand, lawyers might well advise retained experts to submit manuscripts to journals having the least restrictive requirements in order to minimize feedback that may be misinterpreted by a jury. Courts are unlikely to permit extensive explorations about the relative standing of different publications in the midst of already complicated trials. *See* Fed. R. Evid. 403. Making peer review a condition, however, may ultimately be self-defeating in terms of the objective sought—improving the quality of the scientific claims urged in litigation.

For these reasons as well as the practical concerns noted earlier, submission to peer review should be regarded as a favorable attribute, but the lack of peer review should not be treated as a conclusive factor mandating exclusion of an expert.

CONCLUSION

In this brief, *amicus* has explored the various postures in which courts must deal with issues posed by the introduction of scientific evidence into the courtroom. Our objective has been to delineate more precisely when law should defer to science, and when science must give way to the law. The tests that judges currently use in ruling on the admissibility of expert proof grounded in science are not adequately geared to the nature of the scientific enterprise. We propose a new set of criteria that would enable the product of a recognized form of scientific inquiry to be utilized more effectively in decision making in the federal courts.

For the foregoing reasons, the Court should clarify the standard to be used in determining the admissibility of scientific evidence.

Respectfully submitted,

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[1] The views of the members of the Carnegie Commission on Science, Technology, and Government reflected herein are personal views, are not made in their professional capacities and do not reflect the views of their affiliates.

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IN THE
Supreme Court of the United States

October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, Individually And As Guardians Ad Litem For JASON DAUBERT, and ANITA DE YOUNG, Individually And As Guardian Ad Litem For ERIC SCHULLER
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC,
Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF AMICUS CURIAE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF PETITIONER

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IN THE
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No. 92-102

WILLIAM DAUBERT and JOYCE DAUBERT, Individually And As Guardians Ad Litem For JASON DAUBERT, and ANITA DE YOUNG, Individually And As Guardian Ad Litem For ERIC SCHULLER
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On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

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BRIEF OF AMICUS CURIAE ASSOCIATION OF TRIAL LAWYERS OF AMERICA IN SUPPORT OF PETITIONERS

IDENTITY AND INTEREST OF *AMICUS CURIAE*

The Association of Trial Lawyers of America ["ATLA"] is a voluntary national bar association whose approximately 60,000 members primarily represent injured plaintiffs in civil actions.

Written consents of both parties to the filing of this brief have been filed with the Clerk of the Court.

Litigation of claims by injured victims frequently demands testimony by qualified experts to assist the jury in making factual determinations. The decision below, which sets up a new barrier to the admissibility of expert opinion, is therefore of grave concern to ATLA members.

The Seventh Amendment of the Constitution guarantees the right of litigants to have factual disputes decided by the jury. The Federal Rules of Evidence were intended to effectuate this right by removing judicial barriers to expert testimony that would assist the jury in its deliberations. In ATLA's view, the lower court's requirement that expert opinion be "peer reviewed" as a condition of admissibility not only exceeded the court's authority under the Federal Rules, but also deprived plaintiffs of the constitutionally protected right to trial by jury.

SUMMARY OF ARGUMENT

The authority of federal judges to exclude expert witness testimony from consideration by the jury in a civil case is limited, not only by the Federal Rules of Evidence, but also by the Seventh Amendment to the Constitution.

The right to trial by jury has been deemed fundamental to our system of justice and incorporated into the Constitution as an important limitation on the power of government, particularly of the judiciary. This Court has long viewed any curtailment of that right with close scrutiny.

An essential element of this right is the role of the jury in assessing the credibility of witnesses and the weight of their testimony. In this case, the lower court excluded expert opinion on the grounds that the experts' conclusions disagreed with the opinions of virtually all other experts in the field and had not been published and subjected to peer review. The court's analysis confused general acceptance of a

scientific technique or methodology, a question historically allocated to the judge, with general acceptance of the conclusions reached by a particular application of the technique or methodology. That issue goes to the credibility or weight of the evidence and is reserved for the jury.

The lower court's novel requirement for the admission of expert opinion is inconsistent with the provisions and purpose of the Federal Rules of Evidence. Moreover, since the Rules have relieved federal judges of the power to create new common-law rules of evidence, the court's action exceeded its judicial authority and intruded upon the role of Congress.

By delegating the determination of the admissibility of expert opinion to the extra judicial process of peer review, the court plainly violated the Seventh Amendment prohibition against reexamination of factual matters other than according to the rules of common law.

ARGUMENT

I. THE SEVENTH AMENDMENT REQUIRES CAREFUL SCRUTINY OF ANY CURTAILMENT OF THE RIGHT TO TRIAL BY JURY BY THE FEDERAL JUDICIARY.

The role of the judge with respect to the admissibility of evidence is broad, but not unbounded. The Federal Rules of Evidence, promulgated by this Court and enacted into law by Congress, govern the admissibility of evidence in federal courts. However, the authority to exclude evidence and thereby preclude a jury determination of disputed factual issues is limited, ultimately by the Seventh Amendment.

In this case, plaintiffs' proposed expert testimony on the issue of causation was clearly relevant, under Fed. R. Evid.

401. It appears undisputed that the experts possessed sufficient qualifications under Fed. R. Evid. 702 and that the testimony was based on facts or data of a type reasonably relied upon by experts in the field, under Fed. R. Evid. 703. Nonetheless, the lower court ruled the proposed testimony inadmissible because the experts' assessment of the underlying data had not been published and subjected to peer review. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128, 1131 (9th Cir. 1991). Amicus suggests that the lower court exceeded the clearly defined bounds of judicial authority and thereby violated plaintiffs' right to trial by jury under the Seventh Amendment.

The Seventh Amendment provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of common law.

U.S. Const., amend vii.

Congress has restated this guarantee even more forcefully for federal courts:

> The right of trial by jury as declared by the Seventh Amendment to the Constitution or as given by a statute of the United States shall be preserved to the parties inviolate.

Fed. R. Civ. Pro. 38(a).

The importance of the right to trial by jury in our justice system can scarcely be overstated. The jury, in the Founders' view, is no mere nicety, but an indispensable safeguard of limited government. It represents, in the words of Jefferson, "the only anchor yet imagined by man, by which a

government can be held to the principles of its constitution." The Writings of Thomas Jefferson 71 (Washington ed. 1861). Indeed, the strong objections to the absence of an explicit guarantee of the right to trial by jury sparked the demand for a Bill of Rights as a condition to ratification of the constitution itself. Henderson, *The Background of the Seventh Amendment*, 80 Harv. L. Rev. 289, 298 (1966); C. Wolfram, *The Constitutional History of the Seventh Amendment*, 57 Minn. L. Rev. 639, 657-59 (1973).

This Court has historically championed the right to trial by jury and has viewed any infringement with great disfavor. Describing the right to trial by jury as "a great constitutional right", this Court stated that "it is only in exceptional cases and for specific causes that a party may be deprived of it." *Grand Chute v. Winegar*, 82 U.S. 373, 375 (1872). *See also, Bailey v. Central Vermont Ry.*, 319 U.S. 350, 354 (1943) ("The right to trial by jury is a basic and fundamental feature of our system of federal jurisprudence"); *Lyon v. Mutual Benefit Assoc.*, 305 U.S. 484, 492 (1939) ("It is essential that the right to trial by jury be scrupulously safeguarded"); *Dimick v. Schiedt*, 293 U.S. 474, 486 (1935) ("any seeming curtailment of the right to a jury trial should be scrutinized with the utmost care.")

The specific target of the Seventh Amendment, as reflected by the constitutional text, is the power of the judiciary, reflecting the colonists' bitter experience with autocratic judges. *See*, R. Pound, The Development of Constitutional Guarantees of Liberty 69-72 (1957); M. Arnold, *A Historical Inquiry Into the Right to Trial By Jury in Complex Civil Litigation*, 128 U. Pa. L. Rev. 829, 832-35 (1980). As a result,

> The founders of our Nation considered the right of trial by jury in civil cases an important bulwark against

> tyranny and corruption, a safeguard too precious to be left to the whim of the sovereign, or, it might be added, to that of the judiciary.

Parklane Hosiery Co. v. Shore, 439 U.S. 322, 343 (Rehnquist, J., dissenting). *See also Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 83 (1989)(White, J., dissenting)("The function of the civil jury is to diffuse the otherwise autocratic power and authority of the judge"). The Seventh Amendment's restraint on judicial power continues to be vital. As Judge Patrick Higginbotham points out, "American federal courts . . . have a peculiar need for the democratizing influence of the jury" because an independent judiciary, essential to judicial review, also carries "its attendant risk of autocratic behavior." P. Higginbotham, *Continuing the Dialogue: Civil Juries and the Allocation of Judicial Power*, 56 Texas L. Rev. 47, 52 (1977).

Amicus suggests that the exclusion of plaintiffs' expert testimony in this case represents precisely the type of judicial excess that the Seventh Amendment was designed to guard against.

II. THE LOWER COURT IMPERMISSIBLY USURPED THE JURY'S FUNCTION IN ASSESSING THE CREDIBILITY OF EXPERTS AND THE WEIGHT OF EXPERT TESTIMONY.

A. The Seventh Amendment Protects The Right of Litigants To Jury Determinations Concerning Credibility of Witnesses And Weight Of Evidence.

The Seventh Amendment protects only "those incidents which are regarded as fundamental" to the system of trial by jury. *Tull v. United States*, 481 U.S. 412, 426 (1987). One such fundamental incident, indeed the central function of the

jury, is the evaluation of the evidence in reaching findings of fact. This Court has instructed:

> It is the jury, not the court, which is the factfinding body. It weighs the contradictory evidence and inferences, judges the credibility of witnesses, receives expert instructions and draws the ultimate conclusion as to the facts. . . Its function is to select among conflicting inferences and conclusions that which it considers most reasonable. That conclusion, whether it relates to negligence, causation, or any other factual matter cannot be ignored.

Tennant v. Peoria & Pekin Union Ry., 321 U.S. 29, 35 (1944). *See also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)("Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of the judge."); *Barefoot v. Estelle*, 463 U.S. 880, 902 (1983)("the fundamental premise of our entire system [is] that the purpose of the jury is to sort out the true testimony from the false, the important matters from the unimportant matters, and when called upon to do so, to give greater credence to one party's expert witnesses than another's.").

Of particular import in this case is Justice Black's caution in *Galloway v. United States*:

> A verdict should be directed, if at all, only when, without weighing the credibility of the witnesses, there is in the evidence no room for honest difference of opinion over the factual issued in controversy. I shall continue to believe, that in all other cases a judge should, in obedience to the command of the Seventh Amendment, not interfere with the jury's function. Since this is a matter of high constitutional importance, appellate courts should be alert to insure the preservation of this constitutional right.

319 U.S. 372, 407 (1943)(Black, J., dissenting). The price of the lack of such vigilance has been "the 'gradual process of judicial erosion which . . . has slowly worn away a major portion of the essential guarantee of the Seventh Amendment.'" *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 339 (1979)(Rehnquist, J., dissenting), quoting Justice Black in *Galloway*, 319 U.S. at 397.

B. The Lower Court's Exclusion of Plaintiffs' Expert Testimony Was Based On Judicial Assessment of Weight and Credibility.

The focus of the Ninth Circuit's decision is the proffered opinion testimony by plaintiffs' expert witnesses that Bendectin caused plaintiffs' birth defects. That opinion was based, in part, on the experts' reanalyses of epidemiological data gathered by others, leading them to conclusions which differed from those reached by the scientists who analyzed the data originally. *Daubert*, 951 F.2d at 1130.

The court ignored the fairly clear criteria set forth by the Federal Rules of Evidence with respect to the admissibility of expert testimony. It made no determination that plaintiffs' experts lacked sufficient qualifications under Rule 702 or that the underlying facts or data were not of the type reasonably relied upon by experts in the particular field under Rule 703. Instead, the court focused on the methodology of reanalysis of epidemiological studies. This, the court stated, was a "scientific technique" that "is admissible if it is generally accepted as a reliable technique among the scientific community." *Id.* at 1129, citing *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923).

Whether the *Frye* test continues to be applicable at all after the enactment of the Federal Rules of Evidence is ably addressed in the Brief of Petitioners. A more fundamental error in this case lies in the peculiar application of the test. The court makes pointed reference to defendant's proffered

evidence that a survey of "more than 30 published studies . . . concluded that no published epidemiological study had demonstrated a statistically significant association between Bendectin and birth defects." 951 F.2d at 1129. The court further found "the methodology particularly problematic in light of the massive weight of the original published studies supporting the defendant's position." *Id.* at 1130.

Neither the court's discussion nor the studies cited purport to address the reliability of reanalysis of epidemiological data. Nor does the court explain why reanalysis should be deemed less reliable than original analysis. The court established only that a substantial number of experts have reached a different conclusion. Amicus submits that this choice between competing expert opinions is one which should have been made by the jury.

The court then states that the reanalyses do not meet the "general acceptance" standard because "they were unpublished, not subjected to the normal peer review process, and generated solely for use in litigation." *Id.* at 1131. Setting aside the question of whether publication and peer review in fact guarantee reliability, an issue explored in depth in Brief of Amici Curiae American Society of Law, Medicine and Ethics, they are not part of the methodology of reanalysis. At most, they indicate acceptance of the particular study by an undefined segment of the scientific community. This, like the previous point, represents little more than a nose-count of those who disagree with the particular results. In short, the court has entangled general acceptance of an expert's methodology with general agreement with the expert's conclusions.

The Ninth Circuit's rationale for shielding the jury from the proffered testimony was to prevent "confusing the issues" or "misleading the jury" because of the "aura of special reliability and trustworthiness" of scientific evidence. *Id.* at 1130. This Court issued a strong denunciation of such

paternalistic reasoning in *Barefoot v. Estelle*, 463 U.S. 880 (1983). The Court there was called upon to decide the propriety of admitting psychiatric testimony used to predict a defendant's future dangerousness. Despite virtually unanimous expert opinion that such evidence was accurate only one out of three times, this Court held that the testimony was admissible at trial.

> All these professional doubts about the usefulness of psychiatric predictions can be called to the attention of the jury. Petitioner's entire argument . . . is founded on the premise that a jury will not be able to separate the wheat from the chaff. We do not share in this low evaluation of the adversary process. . . .

Id. at 899.

Other courts -- even those which espouse the "general acceptance" criterion, have recognized and respected the distinction between general acceptance of a scientific technique and general agreement with the conclusions that a particular expert might reach. As the District of Columbia Court had occasion to explain, satisfaction of this criterion

> begins -- and ends -- with a determination of whether there is general acceptance of a particular scientific methodology, not an acceptance, beyond that, of particular study results based on that methodology.

Ibn-Tamas v. United States, 407 A.2d 626, 639 (D.C. 1979). The court subsequently applied this sound principle in an appeal similar to the case at bar, reinstating a jury verdict in favor of a child born with limb defects. Plaintiff's expert had testified that Bendectin causes such defects. The fact that the testimony of opposing experts "revealed a disagreement as to how the epidemiological and other data should be interpreted" was a "battle in which the jury must decide the

issue." *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100, 1110 (D.C. 1986).

The Fifth Circuit has also addressed this issue:

> Rachelle merely argues that because the notion that chloramphenicol can cause leukemia without first causing aplastic anemia has not been widely accepted in the medical field, the opinions of the Osburns' experts that Mr. Osburn's leukemia was caused by exposure to chloramphenicol provide insufficient evidence of causation.
>
> This argument misses the point. An expert's opinion need not be generally accepted in the scientific community before it can be sufficiently reliable and probative to support a jury finding . . . . What is necessary is that the expert arrived at his causation opinion by relying on *methods* that other experts in his field would reasonably rely upon in forming their own, possibly different opinions, about what caused the patient's disease.

Osburn v. Anchor Laboratories, Inc., 825 F.2d 908, 915 (5th Cir. 1987). *See also Peteet v. Dow Chemical Co.*, 868 F.2d 1428, 1433 (5th Cir. 1989)(As long as an expert's methodology is well-founded, the nature of the expert's conclusion is irrelevant to admissibility, even if it is controversial or unique).[1]

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[1]In *Christophersen v. Allied Signal Corp.*, 939 F.2d 1106 (5th Cir. 1991), the court appears to have imposed tighter judicial control over expert opinion, -- so tight that a vigorous and well-reasoned dissenting opinion accused the majority of "taking over" the role of deciding the reliability and weight of expert opinion in violation of the right to trial by jury. 939 F.2d at 1126 (Reavley, J., dissenting). Nevertheless, the court specifically reaffirmed the principle stated in *Osburn* and *Peteet* that where the parties' experts rely on the same methodologies but draw opposite conclusions from the available information, "a jury must be allowed to make credibility determinations and weigh the conflicting evidence." 939 F.2d at 1111.

Similarly, in *In re Swine Flu Immunization Product Liability Litigation*, 533 F. Supp. 567 (D. Colo. 1980), the district court ruled that expert opinion, based on epidemiological studies, that the vaccine caused Guillain-Barre Syndrome was admissible. The court found that the methodology used by the expert was one that was generally accepted. The fact that the results of the study had not been generally accepted by the medical community, the court stated, affected the weight, not admissibility of the expert's opinion. *Id.* at 578-79.

III. THE LOWER COURT'S DELEGATION OF THE DETERMINATION OF RELIABILITY OF EXPERT OPINION TO THE EXTRA JUDICIAL PROCESS OF PEER REVIEW VIOLATES THE SEVENTH AMENDMENT.

A. The Establishment of a New Rule of Evidence Inconsistent With the Federal Rules of Evidence Exceeded the Court's Authority.

The Ninth Circuit, though purporting to apply the *Frye* test, in fact establishes a novel and unprecedented condition to the admissibility of expert testimony. The expert's methodology "must meet *all* of the essential requirements" that are "imposed by the scientific community" including publication and peer review. 951 F.2d at 1131.

The Seventh Amendment precludes judges from reexamining any fact tried by a jury other "than according to the rules of common law." *See, e.g. Galloway v. United States*, 319 U.S. 372 (1943)(upholding the constitutionality of directed verdicts). The Federal Rules of Evidence are themselves subservient to the commands of the Constitution. Fed. R. Evid. 402. The lower court, however, does not attempt to bring its ruling within the scope of the Rules and is in conflict with them.

Common-law judges burdened the admissibility of expert testimony with a variety of artificial requirements. For most of this Century, leading evidence scholars vigorously criticized these judge-made rules as barriers to the truth-finding function of juries. *See, e.g.*, 3 J. Wigmore, Evidence §688 (1940); Morgan, *Suggested Remedy for Obstructions to Expert Testimony by Rules of Evidence*, 10 U. Chi. L. Rev. 285 (1943); P. Rheingold, *The Basis of Medical Testimony*, 15 Vand L. Rev. 473, 475 (1962).

The enactment of the Federal Rules of Evidence in 1975 represents a general abolition of many of these common-law barriers. *See* J. Weinstein, *Improving Expert Testimony*, 20 U. Rich. L. Rev. 473 (1986); Imwinkelried, *Federal Rule of Evidence 402: The Second Revolution*, 6 Rev. of Litig. 129 (1987). This Court's decisions under the Rules have consistently upheld the Rules' preference in favor of broad admissibility of scientific evidence and confidence in the jury's ability, aided by cross-examination and the adversarial process, to carry out its factfinding function. *E.g., Rock v. Arkansas*, 483 U.S. 44, 61 (1987); *see* R. Jonakit, *The Supreme Court, Plain Meaning, and the Changed Rules of Evidence*, 68 Tex. L. Rev. 745, 764-67 (1990).

The Ninth Circuit's new rule is plainly inconsistent with both the language and purpose of the Federal Rules of Evidence and does not enjoy any presumption of constitutionality that might attach to the Rules. Indeed, its infringement of the right to trial by jury warrants close scrutiny. *Dimick v. Schiedt*, 293 U.S. 474, 486 (1935).

The lower court's ruling suffers an even more basic error: The enactment of the Rules removed the authority of federal judges to create new rules of evidence in the manner of the common law. It was the intent of Congress to create a uniform and "comprehensive code of evidence" for federal courts. S. Rep. No. 93-1277, 93rd Cong., 2d Sess. (1974). As a result, "under the Federal Rules, no common law of

evidence remains." *United States v. Abel*, 469 U.S. 45, 50 (1984). *See also* Imwinkelried, *The Meaning of Probative Value and Prejudice in Federal Rule of Evidence 403: Can Rule 403 Be Used to Resurrect the Common Law of Evidence?*, 41 Vand. L. Rev. 879, 881-83 (1988). This development was recognized by the Ninth Circuit, in an earlier time. *United States v. Grajeda*, 570 F.2d 872, 874 (9th Cir. 1978)("the courts are not free to establish rules of evidence independent of the Federal Rules.")

Amicus suggests that if the admissibility of scientific evidence under the Rules poses a problem for federal courts, it is a matter for Congress, not individual federal judges, to resolve.

B. The Delegation of Admissibility of Scientific Evidence to the Process of Peer Review Violates the Seventh Amendment.

Historically, judicial barriers to expert opinion have had the effect of removing reliability determinations from the jury box to the judge's bench. The lower court's rule removes those determinations from the courtroom entirely. Under the announced rule, the admissibility of expert opinion such as that proffered by plaintiffs in this case, is to be determined by an indeterminate segment of the scientific community engaged in publication and "peer review" entirely apart from and unaccountable to the judicial process.

Peer review, whatever its benefits to the world of science, does not constitute reexamination of fact "according to the rules of common law" under the Seventh Amendment. Amicus submits that the exclusion of plaintiffs' expert testimony on that basis deprived them of the right to trial by jury.

CONCLUSION

For these reasons, Amicus urges this Court to reverse the judgment of the Court of Appeals for the Ninth Circuit.

Respectfully submitted,

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IN THE
Supreme Court of the United States

October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT,
Individually And As Guardians Ad Litem For
JASON DAUBERT, and ANITA DE YOUNG, Individually
And As Guardian Ad Litem For ERIC SCHULLER
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.
Respondent.

**On Writ Of Certiorari To The
United States Court Of Appeals For The Ninth Circuit**

**BRIEF OF AMICI CURIAE
DARYL E. CHUBIN, Ph.D.
EDWARD J. HACKETT, Ph.D.
DAVID MICHAEL OZONOFF, M.D., M.P.H.
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THE INTERESTS OF THE *AMICI CURIAE*

All four amici are scholars with wide-ranging experience in the fields of medicine, epidemiology, history of medicine, history of science, and sociology of knowledge. **Daryl E. Chubin**, a Senior Associate and Project Director in the Science, Education, and Transportation Program, Office of Technology Assessment, U.S. Congress, and **Edward J. Hackett**, an Associate Professor in the Department of Science and Technology Studies at the Rensselaer Polytechnic Institute, are the co-authors of PEERLESS REVIEW: PEER REVIEW AND U.S. SCIENCE POLICY (1990), which has been widely hailed as the most definitive text on the strengths, weaknesses, operations, purposes, and principles of and the controversies surrounding the peer review system. Both Chubin and Hackett have participated in the peer review system as authors published by peer review journals, as "referees" who have reviewed articles submitted to such journals by other writers, and as editors of such journals, as well as speaking and publishing at various scholarly, but not peer review, fora.[1]

David Michael Ozonoff is the Chair of the Department of Environmental Health at the Boston University School of Public Health and Professor of Public Health as well a Professor in the Department of Socio-Medical Science and Community Medicine at the Boston University School of Medicine. **Richard W. Clapp** is the Director of the Center for Environmental Health Studies for John Snow, Inc. in Boston, an Assistant Clinical Professor at Tufts University School of Medicine and an Adjunct Assistant Professor at Boston University School of Public Health. Like Chubin and Hackett, Ozonoff and Clapp have participated in the peer review system as authors, editors, and referees, and, like their fellow *amici*, have spoken and written widely at a variety of scholarly, but not peer review, fora. In addition, both Ozonoff and Clapp have provided testimony as expert witnesses at numerous trials and depositions.

None of the *amici* have an interest in either the outcome of this case or the outcome of other so-called "Bendectin cases". *Amici* seek to advise the Court that the decisions below were premised on a fundamental misunderstanding of the peer review

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[1] A more detailed description of the positions held by and qualifications of the amici are set forth in the attached Appendix.

system, a misconception that has the potential of distorting both the way trials are conducted and the way in which the peer review system operates. If federal courts intend to base decision regarding the admissibility of expert opinion testimony on determinations made by the editors and referees of peer review journals, these courts ought understand how the peer review journal system functions and the weaknesses as well as the strengths of that system. The need to understand these matters transcends the interests of the parties in this case and the unique perspectives of the *amici* might not otherwise be brought to the attention of the Court.[2]

SUMMARY OF ARGUMENT

The peer review system[3] has many virtues. Serving as a litmus test for truth, as a guarantor of scientific certainty, and as the gatekeeper for expert witnesses for the litigation process are not among them. The peer review system was not designed to serve those functions, makes no claims to do so, and, at least as presently instituted, is incapable of performing those tasks. The purposes of the journal peer review system in science are to screen for obvious errors in methodology and reasoning, and to ensure that the research is novel and "important." The peer review system serves those purposes well, but, like other tools, its utility is marginalized when it is employed for purposes for which it was not designed. For example, the peer review system is not a truth certification process, nor does it guarantee that the particular data, research and analytical methodologies, or conclusions of the

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[2] Counsel for all parties have consented to the filing of this *amicus* brief. Letters of consent have been filed with the Clerk of the Court.

[3] The term "peer review system" is used to describe the system of submitting, reviewing (or refereeing), and editing papers intended for publication to "peer review journals," as distinct from the system of using peer review referees to judge proposals for research grants, *i.e.*, "grants peer review." See Daryl E. Chubin and Edward J. Hackett, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY 1-15 (1990).

accepted papers represent the consensus opinion of the relevant community.

Each of the amici has carefully read the decisions filed by the United States Court of Appeals for the Ninth Circuit and the United States District Court for the Southern District of California in this case as well as the petition for certiorari, the respondent's opposition to the petition, and the petitioners' reply brief. We are troubled by the portions of those decisions that purport to describe and use the peer review system as tools in the litigation process. We are troubled by the lower courts' decision to rely -- exclusively -- on peer review journals to determine whether an expert witness can be allowed to testify before a jury and what he or she may say if allowed to testify. We believe that the lower courts' misunderstanding of the peer review system led them to devise and ordain two mischievous presumptions: an apparently rebuttable presumption that anything that is published in a peer review journal is "good science" and therefore admissible; and, conversely, an evidently irrebuttable presumption that unless a theory, fact, and analysis has been previously published in a peer review journal such ideas and information cannot be "good science" and cannot form the basis for admissible expert testimony.

We are also disturbed by the fact that the lower courts rendered those decisions without an accurate understanding of the peer review system and, apparently, without any factual background concerning that system. We cannot understand why the lower courts made such a choice and we have read nothing in the lower courts' decisions that explains their reasoning.[4]

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[4] We were surprised to see that the courts below did not cite a single scientific authority in support of their rulings on these points. The sole authority mentioned, Peter Huber, is not known to be either a scientist or a scholar. Indeed, it seems as if the zeal with which the courts below embraced the peer review system can only be explained by their obliviousness about the controversies about the peer review system that have roiled the academic and scientific communities for at least the last half-dozen years. Thus, "there is mounting evidence that peer review in the United States is not functioning well, and there is growing concern among scientists and policymakers about the soundness of the peer review system." Daryl E. Chubin and Edward J. Hackett, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY (1990), at 1. SEE ALSO THE PROCEEDINGS OF THE FIRST INTERNATIONAL CONFERENCE ON PEER REVIEW IN

(continued...)

Before we endeavor to suggest where the lower courts erred in the understanding of the peer review system and before we describe what we believe to be the real strengths and not inconsiderable weaknesses of that system, we must confess that we are unqualified to offer this Court any guidance concerning the legal issues presented by the petition for certiorari filed in this case: whether the common law test for admissibility of expert opinion testimony that originated with *Frye v. United States*, 293 F. 1013 (1923), survived Congress' enactment of a rule of evidence that deals with the same subject, whether federal judges possess some sort of inherent power that they can employ to supplement whatever rules are enacted by Congress, and whether the U.S. Constitution authorizes federal judges to devolve to the editors of peer review journals (and to the anonymous referees who are hand-picked by those editors) decisions about what is (and what is not) so-called "good science" and regarding which expert witnesses can be allowed to testify in criminal and civil cases.[5]

Moreover, although we have made some efforts to familiarize ourselves with the underlying factual controversy in this case (having gone so far as to read, among other things, the affidavits and curriculum vitae submitted to the District Court by the plaintiffs' experts and the defendant's expert), we also acknowledge that we can offer no help in helping to decide whether Bendectin can cause birth defects, in general, and whether Bendectin caused the birth defects that the plaintiffs-petitioners allegedly suffered, in particular. Thus, if we were today to be seated as jurors in this case we could not be say who should prevail

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[4](...continued)
BIOMEDICAL RESEARCH, May 10-12, 1989 (Many of the papers presented at the conference were printed in an issue of the Journal of the American Medical Association specially devoted to that topic. 263 J. AMER. MED. ASS'N No. 10 (1990).)

[5] We do think it odd, however, that federal judges, who are pledged to uphold a Constitution that emphasizes such principles of due process of law as public access and accountability should be so eager to consign threshold questions of who can testify and what they can say to the self-selected editors of private journals, whose decisions are largely shrouded from view and totally insusceptible to appeals.

-- not unless we had heard all the experts testify and not unless we had seen these same experts cross-examined under oath.

Why, then, have we been vexed to involve ourselves in this matter and why do we think that the Justices of this Court should pay any mind to what we have to say? The reason is simple. We are knowledgeable about the peer review process and its useful contributions to the dissemination of scientific learning. But, because we appreciate the system's limitations as well as its advantages, we believe that the burden placed by the lower courts on the peer review system is a weight that system cannot bear. If we were sitting on a jury in a case such as this, we assuredly would think it important to learn what articles had been written, pro and con, about the issues in dispute. Nevertheless, in general, we do not think that the fact that one expert could point to a published article in support of his views and the fact that another expert could not cite a published article in support of her views would be the acid test in our decision-making. We do not think that such facts should be the acid test for the decision-making.

Such facts *might influence*, to a greater or lesser degree, our preliminary decision about which expert(s) to believe, but we would not allow our decisions on this sort of threshold issue to turn on a single fact such as publication or non-publication. In our view, the lower courts did not truly comprehend how the peer review system does (and does not) work, how well (and how poorly) the system operates, and what are the system's true strengths (and its not inconsiderable weaknesses). If the lower courts had understood the system as we do they would not have relied on it as a shortcut for and they certainly would not have proposed to rely on it as he exclusive indicator of reliable and valid expert testimony.

Although it is appropriate for courts to use the peer review system to help guide the decisions of judges and jurors, courts should not rely on solitary facts -- such as publication, multiple publication, publication in prestigious journals, or non-publication -- as the exclusive determinant of whether an expert has anything useful to say and whether that expert should be allowed to testify. The temptation to rely upon the peer review system to provide a quick fix for the sometimes irritating and frequently time-consuming problems presented by cases that involve complicated questions of science may be a understandable one. But this impulse to rely

exclusively on peer review literature (and its interpreters), like many ideas born of frustration, should be resisted. This temptation should be resisted because the allure of relying on the peer review system is based on ignorance of and myths about that system, not knowledge and understanding of it. The lure of the peer review system stems from six largely erroneous beliefs, myths that gain no validity from the fact that they may be widely held. As discussed at length below, none of these myths can withstand serious scrutiny.

First, the peer review system is not intended to yield "the truth, the whole truth, and nothing but the truth." ***Second***, peer review journals do not replicate and verify the experiments, research and analytical techniques, or data reported in the papers submitted for publication. ***Third***, peer review journals do not warrant that the ideas and information contained in the articles they publish are accurate, valid, certain, reliable, or true, or otherwise amount to "good science." ***Fourth***, the mere fact of publication does not mean that the ideas and information reported in an article are "generally accepted" by, or represent the "consensus" views of, the relevant academic community. ***Fifth***, conversely, the fact that ideas and information have not been published in a peer review journal does not mean that they are not "generally accepted", or that they are "generally rejected", or that they cannot represent "good science." ***Finally***, the peer review system should not be regarded as more rigorous and reliable than the jury system's use of cross-examination. For these reasons, the courts should not rely exclusively on peer review literature, but should consider peer review literature in conjunction with other materials and with expert testimony.

In sum, the courts should not put all of their eggs in the peer review basket.

ARGUMENT

I. CONTRARY TO POPULAR MYTH, THE PURPOSES AND DESIGN OF THE PEER REVIEW SYSTEM ARE *NOT* TO PRODUCE "THE TRUTH, THE WHOLE TRUTH, AND NOTHING BUT THE TRUTH."

Although witnesses are obliged to swear to "tell the truth, the whole truth, and nothing but the truth," the litigation process overall does not seek absolute truth but, instead, a much more modest, yet still quite challenging goal -- providing justice to the parties to a case.[6] Similarly, although the overarching goal of the peer review system may be to add to the total sum of scientific knowledge and to the grand scheme of scientific understanding of the universe, the practical and immediate purposes, and the concomitant operation, of the peer review system are much more modest. "Briefly defined, peer review is an organized method for evaluating scientific work which is used by scientists to certify the correctness of procedures, establish the plausibility of results, and allocate scarce resources (such as journal space, research funds, recognition, and special honor)." Daryl E. Chubin and Edward J. Hackett, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY 2 (1990). The primary goal of the peer review system is to provide a relatively permanent and readily accessible documentary record of ongoing scientific research and analysis, that is, printed reports rather than anecdotal or apocryphal accounts, and thus to facilitate the development and exchange of ideas.[7] The

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[6] If our legal system genuinely aimed for "the whole truth and nothing but the truth," it would have to jettison numerous rules, traditions, and doctrine that substantially interfered with the fulfillment of that goal. Thus, the courts would need to repudiate virtually all privileges (whose major function is to limit the information that is available to the trier of fact), statutes of limitation and statutes of repose, all limitations on discovery, in both civil and criminal cases, as well as such constitutional criminal law precepts as the Exclusionary Rule and the *Miranda* doctrine.

[7] The incidental purpose of the peer review system is to add to the reputations and enhance the careers of authors, referees, and editors, thereby (continued...)

peer review system is designed to compel authors of such reports to comply with certain minimal formal and stylistic standards in order to weed out essays that appear facially implausible, indefensible, erroneous, fallacious, or fraudulent. The articles that survive the screening process are presented in a standardized format in journals that are made readily available to all scholars and practitioners in a particular discipline, who may then use them in their own work or may challenge them in their own writing, *e.g.*, by attempting to replicate the experiments described or to reanalyze the results reported. Thus, the peer review system is designed to provide a common and convenient *starting point* for scientific debate, not the *final summation* of existing scientific knowledge.[8]

In a nutshell, the peer review system is not designed, and does not function, to add absolutely true, complete, and definitive chapters to the mythical encyclopedia of knowledge. Instead, the peer review system provides a more practical and still extremely valuable service – to furnish, in a timely fashion, interim progress reports of ongoing research experiments, promising investigatory techniques and methodological protocols, useful analytical tools, interesting findings, or provocative hypotheses. The provisional nature of science "truths" is reflected in the fact that peer review journals welcome, and frequently publish, articles, comments, and letters to the editor that are critical of the initial article. Thus, each article stands not as the final word on a given subject but as an invitation to or part of a continuing debate, a never-ending

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[7](...continued)
helping them to obtain research grants from government agencies, science foundations, and industrial companies, to win fellowships and prizes, or to gain tenure and promotion.

[8] In this respect, as in a number of others, the peer review system resembles the law review structure. Although there are some rather significant differences (to give but two examples: (1) articles submitted to law reviews are vetted by apprentice student-lawyers, while manuscripts tendered to peer review journals are sifted by experienced scientists; and (2) teams of law review editors spend endless hours in painstaking efforts to check the accuracy of every cite and footnote, while peer review referees can afford to spend no more than a few scant hours in assessing the facial plausibility of a manuscript), the two systems share at least one important feature – neither hold themselves out as the quintessence of professional knowledge and wisdom.

dialogue. As Niels Bohr, one of the great theoretical physicists of the 20th century endlessly reminded his colleagues: "Every sentence I utter must be understood not as an affirmation, but as a question."

The contingent nature of the reports that are published additionally reflects the ever-evolving nature of scientific inquiry, knowledge, and techniques. Science is not a static enterprise and does not stand as a timeless body of fixed truths. Instead, the corpus of scientific knowledge consists of a set of historically-bounded and ever-changing research results that are subject not only to selection, qualification, and interpretation but virtually constant reinterpretation and reanalysis.[9] It is vast oversimplification to suggest that new facts are simply added to old facts to construct an ever-larger temple of scientific knowledge in the same way that additional bricks can be piled atop already laid bricks to form a taller wall. There are no absolute, certain truths in science. As Sir William Osler noted: "No human being is constituted to know the truth, the whole truth, and nothing but the truth; and even the best of men must be content with fragments, with partial glimpses, never the full fruition." THE STUDENT LIFE 122 (1919).

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[9] Significantly, historians of science have emphasized that the path to knowledge is not serene, uncomplicated, or predictable. Thus: "The growth of science represents nothing like an unbroken, steadily ascending progression carrying humanity on its shoulders, as it were. It would be far more realistic to think of the history of science as a continuous, sometimes desperate struggle. . . . To think of the evolution of science as a straightforward continuum, or to associate science automatically with progress, involves a profound misunderstanding of the relationship between science and history – if not of the nature of the historic process itself." Thomas Goldstein, THE DAWN OF MODERN SCIENCE (1980), at 245-46. *See generally* Thomas S. Kuhn, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (2d ed. 1970), a seminal work that "has had a wider academic influence [in any field] than any other book of the last twenty years", PARADIGMS & REVOLUTIONS: APPLICATIONS AND APPRAISALS OF THOMAS KUHN'S PHILOSOPHY OF SCIENCE, Garry Gutting, ed. (1980), at v.

II. CONTRARY TO GENERALLY ACCEPTED BELIEFS, THE EDITORS OF A PEER REVIEW JOURNAL AND THE REFEREES PICKED BY SUCH EDITORS TO REVIEW A SUBMITTED MANUSCRIPT DO NOT REPLICATE AND VERIFY THE EXPERIMENTS, TECHNIQUES, ANALYSES, OR DATA REPORTED IN SUCH MANUSCRIPTS

The myth prevails, at least among non-scientists, that the peer review system subjects articles submitted for publication to scrutiny at least as exacting as that of a recipe submitted to GOURMET magazine, a new model car reviewed by the professional drivers and automotive engineers employed by CAR AND DRIVER, or a toaster tested by the editors of CONSUMERS REPORTS. Would that it were so. Although the abilities of the editors and referees of peer review journals are presumptively higher than the talents of those persons who critique recipes, recreation vehicles, and refrigerators (and although the issues are doubtlessly more transcendentally important), the resources -- lab space and testing equipment, money, and time -- available to part-time peer review editors and unpaid volunteer referees for the purpose of scrutinizing the work of other scientists are far less than enjoyed the persons employed by cooking, car, and consumer magazines. Given these stubborn handicaps, peer review referees and editors limit their assessment of submitted articles to such matters *as style*, *plausibility*, and *defensibility*; they do not duplicate experiments from scratch or plow through reams of computer-generated data in order to guarantee *accuracy* or *veracity* or *certainty*. Once again, whatever their desire to do so, they are hampered by financial constraints, and, as noted below, occasionally by ethical restrictions, too.

THE MECHANICS OF THE JOURNAL PEER REVIEW SYSTEM

In order to fully understand how the peer review system operates -- what it does and does not do and what it is and is not capable of doing -- one should know steps leading to the submission of a manuscript, and the mechanics of how it is treated once

it reaches the editor of the journal.[10] Research is a continuing process and it is rare that any particular project has a definite end. Most presentations of the scientific projects, therefore, represent interim progress reports rather than final summaries that analyze all data, address all concerns, and resolve all questions. Accordingly, the decision of whether to publish an interim report to the scientific community by way of a peer review article and, if so, what, where, and when to publish is far more complicated than is popularly supposed.

As a general rule, however, when, in the opinion of the principal investigator(s), a research project has obtained a preordained or otherwise significant result, the progress is written into a manuscript. Upon reviewing the manuscript, the investigators decide, based upon prior experience, which journals are most likely to publish the paper. Assuming that there is more than one such journal, the paper usually is sent first to the editor of the journal with the most prestige or the largest circulation.

Once the submitted paper is received by the journal editor, the formal peer review process begins. The mechanics of peer review vary somewhat from discipline to discipline and from journal to journal, but can be summarized without too much loss of accuracy for the present purposes. Generally, the editor-in-chief or one of his designees has unfettered discretion to select one or two (rarely more) expert referees to pass judgement on the paper. The referees receive the paper together with short checklist on which to score obvious errors, style, length, and plausibility; the referees are commonly given no more than two weeks to return their tally, along with their comments and recommendation for or against publication. This two week period would hardly be sufficient time for the referees to replicate the research, even if

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[10] It should be noted that although the procedures of the review process vary somewhat from journal to journal, the general protocols are made clear to potential authors. Moreover, although the substance of a referee's comments are eventually made known to the author, the identity, affiliations, credentials, and potential biases or conflicts of those reviewers are almost invariably shrouded in cloaks of confidentiality. Thus, although the peer review system may not be a completely closed and secretive procedure, it is generally a one-sided anonymous enterprise. Accordingly, what happens to a manuscript after an editor turns it over to designated referees is virtually immune to objective study.

they were so inclined, even if they possessed the necessary facilities, and even if their own professional lives left them with nothing else to do.

As it happens, however, the unpaid volunteer referees are almost invariably preoccupied with their own research, writing, and teaching and, as a result, typically can dedicate only a few hours *(averaging only 2.4 hours for each manuscript submitted to four of the most influential medical/public health/epidemiological journals)* to read and evaluate the work. In light of these constraints, the referees very rarely, if ever, undertake a rudimentary reanalysis of the data, the experimental or analytical methodology, and the conclusions.[11] Indeed, even *after* a paper has been published, it is rare that scientists will spend their time and money to replicate the results of other scientists – unless they intend disprove the experiments.

Independent replication and verification of a scientific paper – *before publication*, by peer review referees, or *after publication*, by scientists in the field -- may be the ideal; this ideal is, however, rarely achieved in practice. Indeed, the gap between the real and the ideal appears to be widening by the year, as the growing complexity and expense of modern research, and the increasing pressure to publish new results in order to obtain or retain funding

[11] Alfred Yankauer, *Who Are the Peer Reviewers and How Much Do They Review?*, 263 J. OF THE AMER. MED. ASS'N 1338, 1339 (March 9, 1990) (the referees reviewed papers submitted to the NEW ENGLAND JOURNAL OF MEDICINE, the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION THE AMERICAN JOURNAL OF EPIDEMIOLOGY, and the AMERICAN JOURNAL OF PUBLIC HEALTH. *See also* Stephen Lock and Jane Smith, *What Do Peer Reviewers Do?*, 263 J. OF THE AMER. MED. ASS'N 1341, 1342 (1990) (referees for the BRITISH MEDICAL JOURNAL averaged less than two hours reviewing each paper submitted for publication).

for one's own research.[12] Even where replication may be fiscally possible it may be ethically unimaginable.[13]

II. CONTRARY TO THE "GENERALLY ACCEPTED" MYTH, PUBLICATION OF AN ARTICLE IN A PEER REVIEW JOURNAL IS NO ASSURANCE THAT THE RESEARCH, DATA, METHODOLOGIES, ANALYSES, OR CONCLUSIONS DESCRIBED THEREIN ARE TRUE, ACCURATE, VALID, RELIABLE, OR CERTAIN OR THAT THEY REPRESENT "GOOD SCIENCE"

In service of the scientific publication system, the peer review system aims to serve as a mechanism for the timely, widespread, and relatively inexpensive dissemination of information – research, data, methodologies, analyses, or conclusions – produced by some scientists that might be useful to other scientists. "Peer review simultaneously serves several values that are not entirely in harmony. As a *process*, peer review is expected to operate according to values of fairness and expediency, yet its *product* is to be trustworthy, high-quality, innovative knowledge." Chubin and Hackett, *supra*, at 3. In the pursuit of these twin, and somewhat inherently contradictory, goals of providing useful information to as many scientists as possible and as quickly and as cheaply possible, the peer review system is necessarily obliged to make some difficult choices and to accept some perfectly under-

[12] For example, it is theoretically possible but financially inconceivable for referees to independently replicate week-long experimental runs conducted by particle physicists using such mammoth machines as the Fermilab Nuclear Accelerator.

[13] During the 1950s, government scientists knowingly exposed soldiers and sailors to atomic blasts in an effort to gauge the effects of such high doses of radiation on troop performance and morale. Such experiments have since been widely denounced and, in fact, have been the basis of numerous lawsuits, some of which have reached this Court. It is beyond comprehension that any reputable scientist would attempt to replicate these tests today, and certainly not for solitary purpose of verifying reported test results previously submitted for publication to a peer review journal.

standable compromises. "There is no assurance that the process will yield the product; to the contrary, the process may interfere with efforts to secure the product." *Id.*

For example, the peer review system could decide to guarantee, as much as humanly possible, the accuracy, validity, or reliability -- the truth or certainty -- of published articles. To do so, however, might require journals not only to enlist more volunteer referees but actually to hire full-time professional staffs so as to undertake far more difficult, expensive, and time-consuming attempts to replicate the work presented in manuscripts. If the editors followed this course they could more confidently assure readers that the papers published were accurate and true; at the same time, the editors would be obliged to alert their subscribers to the likelihood that fewer papers could scrutinized and published, that such papers could not be published quickly, and, furthermore, that prohibitive price hikes would almost certainly be necessary to defray the vastly-increased cost of independent replication and verification.

At the other extreme, editors might drastically cut costs and minimize delays by publishing the scientific equivalent of a supermarket tabloid -- that is, to print whatever came over the transom, regardless of provenance and regardless of facial implausibility, under the rationale that the readers themselves could sort it all out. Obviously, a middle course has been chosen by most editors and most journals. The point is that in choosing this middle course, compromise is inevitable.

The result of this compromise between absolute certainty, on the one hand, and absolute speed and absolute economy, on the other, this tension between selectivity and sensitivity -- in brief, the tradeoff between filters course and fine -- is that mistakes become inevitable and that erroneous, misleading, and fraudulent reports are sometimes published. The peer review system is not the perfectly reliable mechanism some of its champions claim it to be.

Indeed, some observers have declaimed that many journals rather routinely ignore or tolerate, but in any event reproduce, inaccurate statistics. Thus, as early as 1966, an article in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION disclosed that an analysis of the quality of statistics reports that had appeared in ten different medical peer review journals "suggest[ed] that from a statistical viewpoint, [only] 41 (28%) of 149 [published] studies

were acceptable, 7 (5%) should have been rejected, and 101 (68%) should have been revised before publication," that is, only that submitted manuscripts contained significant errors but that these errors went undetected (or at least uncorrected) by the editors and referees of those ten medical journals. Martin J. Gardner and Jane Bond, *An Exploratory Study of Statistical Assessment of Papers Published in the BRITISH MEDICAL JOURNAL*, 263 J. AM. MED. ASS'N 1355 (1990), *citing* S. Schor and I. Karten, *Statistical Evaluation of Medical Journal Manuscripts*, 195 J. AM. MED. ASS'N 145-50 (1966). Gardner's and Bond's own and more recent study of peer review articles published in the distinguished BRITISH MEDICAL JOURNAL revealed equally alarming results -- only 11% of incoming manuscripts contained accurate statistical reports; that figure improved to 84% after publication. *Id.* (Although some may find such improvement reassuring, one doubts that praise would be heaped on a truck driver who made significant mistakes only 16% of the time, let alone an airline pilot.)

To make matters worse, many if not most journals do not do what the BRITISH MEDICAL JOURNAL routinely does -- independently assess and correct the statistics cited in articles selected for publication. We have good reason to worry what happens to the articles rejected for publication, whether, as is commonly the case, they were submitted to less prestigious and less demanding journals, where the editors and referees lack the time or inclination to check for statistical accuracy[14] and where the articles might eventually be published.[15]

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[14] Thus, a recent survey revealed that although statistical analyses were prominent in 54.1% to 72.7% of the articles published in a sample of American biomedical journals (depending on the classification of the journals by the researchers), the percentage of journals that "always or usually use a statistical review" ranged from 30.5% to 37.5%. Ann C. Weller, *Editorial Peer Review in US Medical Journals*, 263 J. OF THE AMER. MED. ASS'N 1344 (1990).

[15] Another recent study involved sending 25 manuscripts that had been accepted for publication, after review and revision, by the JOURNAL OF PEDIATRICS (but not published at the time) to two additional referees for evaluation. Joseph M. Garfunkel, Martin H. Ulshen, Harvey J. Hamrick, Edward E. Lawson, *Problems Identified by Secondary Review of Accepted Manuscripts*, 263 J. AM. MED. ASS'N 1369 (1990). The researchers discovered that, although

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The failure of peer review journals to adequately screen out false, substandard, or fraudulent reports might be excusable if the journals did a creditable job of subsequently informing their readers about the existence of the published mistakes (and the dangers of relying on reports containing such flaws) once the errors were noticed. Unfortunately, the journals do not do much better after the fact than they do before.[16]

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[15](...continued)
there was substantial agreement between the first and second set of reviewers, "the initial two-part review failed to identify a significant number of concerns that probably should have been corrected, or at least addressed, before publication." *Id.*, at 1370. Still another study checked 150 randomly selected citations and quotations taken from articles published in three medical journals. James T. Evans, Howard I. Nadjari, and Sherry A. Burchell, *Quotational and Reference Accuracy in Surgical Journals*, 263 J. AM. MED. ASS'N 1353 (1990). Forty-eight percent (72) of the citations had some error, while nine percent (13) had major citation errors. Moreover, of the 137 articles with no major citation errors 23% (32) had major quotation errors, sometimes saying that a source supported a particular proposition, when it did not, as for example: "The article by Lowe is cited to support an increased risk of esophagal cancer with alcohol consumption. The article by Lowe is about treatment and contains absolutely no mention of etiology." *Id.*, at 1354.

[16] Inasmuch as the peer review system is conducted by human beings, there is no reason to expect it to be perfect, and it is not. This imperfection would not matter much if major errors were caught quickly and corrected completely. Even after a mistake is discovered, however, it can take *decades* to correct completely. Indeed, peer review journals seem unusually reluctant to acknowledge mistakes and to correct those mistakes that are conceded. For example, one contemporary probe recounts the saga of "unique cell cultures" that were the cause of much celebration when they were discovered a generation ago -- and great use and reliance by many scientists since that time. By the early 1970s, it was learned, though, that the putatively "unique" cultures were anything but. Nevertheless, those portions of the scientific community who were most responsible for the problems (and the ones best situated to rectify the errors) were decidedly reluctant to issue the necessary retractions. For this reason, it is believed that many scientists may still have not received the word and may yet be unaware of the contamination of the cell cultures. Michael Gold, A CONSPIRACY OF CELLS (1986).

More generally, according to a recent report by two investigators: "Little is known about the ultimate scientific fate of retracted, invalid literature. We identified 82 completely retracted articles . . . and measured their subsequent

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Both types of problems -- the initial failure to screen out faulty reports and the subsequent failure to adequately, if ever, inform readers that inaccurate or fallacious articles had been published -- are compounded by the fact that there is no licensing board that sets uniform criteria for what a journal should and should not publish or what a magazine needs to do to qualify as a peer review journal. Along the same lines, although professional basketball referees must go to school to learn what is or is not a foul, peer review journal referees receive no comparable training. Even more amazingly, the peer review industry is a wholly unregulated collection of completely independent and unsupervised periodicals, as there is no licensing board that certifies that a magazine qualifies as peer review journal. Like boilerroom "investment counselors" before the establishment of the Securities and Exchange Commission, calling oneself the editor of a peer review journal simply makes one so. At least, there is no entity to challenge such puffery.

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[16](...continued)
use in the scientific literature . . . . After retraction, these studies were cited, for support of scientific concepts, 733 times [or roughly nine times apiece.] Comparison with a control group revealed that retraction reduced subsequent citation by approximately 35% [only]." Abstract of Mark. P. Pfeiffer and Gwendolyn L. Snodgrass, *The Continued Use of Retracted, Invalid Scientific Literature*, 263 J. OF THE AMER. MED. ASS'N 1420 (1990). As a result, "[i]nvalid work is not being effectively purged from the scientific literature." *See also* Paul F. Friedman, *Correcting the Literature Following Fraudulent Publication*, 263 J. OF THE AMER. MED. ASS'N 1416 (1990).

IV. CONTRARY TO POPULAR OPINION, THE FACT THAT AN ARTICLE HAS BEEN PUBLISHED IN A PEER REVIEW JOURNAL DOES NOT ESTABLISH THAT THE FACTS, RESEARCH OR ANALYTICAL METHODOLOGIES, OR CONCLUSIONS REPORTED THEREIN ARE "GENERALLY ACCEPTED" BY OR REPRESENT THE "CONSENSUS" VIEWS OF THE RELEVANT SCIENTIFIC COMMUNITY

Peer review journals serve the scientific community in much the same way that legal periodicals and law reviews serve the legal community. For example, just as the SECURITIES LAW REPORTER recapitulates important new complaints, newly-promulgated SEC regulations, and new administrative law or court decisions, and just as law reviews offer summaries or analyses of new trends and developments and provide a forum for new theories or proposals, peer review journals recount significant new experiments, investigations, therapies, interpretations, and theories. But peer review journals are not like the "United States Reports" or "RESTATEMENTS OF THE LAW." Unlike the U.S. Reports, peer review journals do not provide the official accounts of authoritative decisions rendered by a body that is constitutionally ensconced and uniformly recognized as the preeminent arbiter of the law. For one thing, there is no Supreme Court of science -- no tribunal that has the power and authority to provide the final opinion on important controversies.[17] Similarly, unlike the RESTATEMENTS, peer review journals do not provide, either singly or collectively, the conclusive and exhaustive syntheses of what a college of the most

[17] Of course, as this Court well knows, no Supreme Court opinion is ever truly "final," at least in the sense that the subject cannot be revisited or that a precedent cannot be overturned. By like token, no Supreme Court decision is "absolutely right," in the sense that it cannot be reversed by a subsequent decision of the Court. Finally, no decision is "generally accepted," at least insofar as it is immune from criticism by everyone from Presidential candidates and elected officials to law professors and even justices of the Supreme Courts of the fifty states. To be sure, some decisions by this Court are unanimous and some decisions by this Court may become, sooner or later, "generally accepted." But few would wager when or if a decision will be generally accepted, and even if it becomes generally accepted, whether it will remain forever in that state of grace.

highly-regarded scholars, judges, and practitioners deem the law is (or ought to be). Furthermore, although there are some organizations of scientists, such as the National Academy of Sciences or the National Research Council, that are roughly comparable to the American Law Institute, the resolutions reached by the former, like RESTATEMENTS agreed upon by the latter, are not always published in peer review journals, nor are such resolutions the only things published in peer review journals.

To reiterate what was emphasized above, papers submitted to peer review journals for publication are accepted not because the peer review journals editors and referees have resolved that the information and ideas contained in the papers -- data, research protocols, analytical constructs, theoretical conclusions -- are necessarily true or immutably right or absolutely accurate or represent some form of scientific consensus, but because they have determined that the information and ideas are plausible and, thus, *may* contribute to the further development of scientific ideas.

Even this point must be qualified. The fact that the referees and editor of one journal have decided that the information and ideas contained in a submitted paper are plausible (or even the fact that they regard such ideas and information as absolutely true, universally valid, and unassailably accurate) does not mean that their judgment has been or would be shared by the editors and referees of other journals, that is, accepted by all or most of the scientific community. Indeed, the opposite may often be the case. A moment's reflection shows why this is so. Although it may well be that an article published in the NEW ENGLAND JOURNAL OF MEDICINE would have been accepted for publication by the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, and vice versa, the number of papers submitted to such prestigious journals is quite large and the number that is accepted is quite small. Although the publication acceptance rate varies from one discipline to another, as well from one journal to another, as a general rule, the more prestigious the journal, the greater are the number of papers submitted and the lower the percentage that are accepted.[18]

[18] In order "[t]o investigate disciplinary differences in how scientific journals evaluate submissions, [one researcher] collected data from the ASTRO-

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Understandably, most authors would prefer to see their articles published in JAMA than in the less renowned publication. Consequently, an author may first take a crack at getting published in JAMA and then, only if failing there, try to have his paper published in a slightly less celebrated journal, and on and on, until the quality of the paper has met its match in the quality of a journal. If the first journal rejects the submitted manuscript, it is sent on to next-best journal and so on, until either the article is published or the author relents. The number of bites at the apple is limited by only two factors: the number of journals in a relevant field and the size of the author's budget for postage. Thus, a

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PHYSICAL JOURNAL, PHYSIOLOGICAL ZOOLOGY, and the AMERICAN SOCIOLOGICAL REVIEW. Referees' evaluations of submissions to these journals differed strikingly: nearly half of the referee reports for American Sociological Review recommended outright rejection, while the corresponding proportions for the other two journals were about one fourth and one tenth. Final dispositions show even greater variation, with the ASTROPHYSICAL JOURNAL accepting 91% of submissions, PHYSIOLOGICAL ZOOLOGY 59%, and AMERICAN SOCIOLOGICAL REVIEW 13%." Abstract of Lowell L. Hargens, *Variation in Journal Peer Review Systems: Possible Causes and Consequences*, 263 J. OF AMER. MED. ASS'N 1348 (1990). *See also* Ann C. Weller, *Editorial Peer Review in US Medical Journals*, J. OF THE AMER. MED. ASS'N 1344, 1346 (1990) (acceptance rates for two broad categories of US medical journals range from 32.8% to 51.8%); Rick Crandall, *Peer Review: Improving Editorial Procedures*, BIOSCIENCE 607 (Oct. 1986)

> In fields like physics, which have acceptance rates of 80%, the rule of thumb [for referees and editors] is, "When in doubt, accept." After a second or third submission, most papers do get published. This high acceptance rate hides the lack of reliability and validity in the process. In fields like psychology, which have acceptance rates of about 20%, the number of papers [submitted] far exceeds the number of pages available. The rule here is, "When in doubt, reject." Those who know the game best enjoy far higher acceptance rates. Through apt choices of topics and methods and good contacts within one's research field, one can succeed.

manuscript may have been rejected by ten or twenty journals before it is finally accepted for publication by one.[19]

By this light, to suggest, as the Ninth Circuit did below, that the appearance of a paper in a peer review journal betokens "general acceptance" by a "consensus" of the scientific community is senseless. If anything, the numerous rebuffs that generally precede eventual acceptance connotes "general rejection" much more than a single endorsement manifests "general acceptance." (To assert or imply that all journals are equally rigorous is nonsense. Indeed, with the proliferation of peer review journals, it is axiomatic that getting a paper published somewhere, at some time, is a virtual certainty, if only one is willing to persevere.) Thus, by the time a paper is finally accepted by a single journal it may have been rejected by countless others.[20]

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[19] Unfortunately, there are few hard numbers on these questions. Although the overall acceptance/rejection rates for journals may be known, individual authors are understandably reluctant to disclose how many times their articles were rejected. By the same token, editors of less-renowned journals are unlikely to advertise the fact that they are in the business of publishing articles that have been rejected by a host of other, "better" journals and that they are, in a fashion, habitually dealing in shop-worn goods.

[20] In fact, whether a paper is accepted or rejected by single journal may depend more on fame or anonymity of the authors (or the relative prestige of the universities or other institutions with which the authors are affiliated) rather than on the quality of the author's work. Caprice and bias may play a much larger role than most champions of the peer review system would wish to acknowledge. *See* Daryl E. Chubin and Edward J. Hackett, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY 94 (1990). Thus, in an illuminating, if somewhat controversial study, two researchers resubmitted a series of twelve previously published articles to the "highly regarded and widely read American psychology journals," journals that had published the same articles 18 to 36 months earlier. The only difference between the articles that had been published and the articles that were resubmitted was that the names and affiliations of the "new" authors had been downgraded. Only three (different) resubmissions were caught, thus allowing nine manuscripts to continue through to the end of the review process. Amazingly, only one of the nine *articles that had been published previously* was accepted for publication the second time around. In each case, all reviewers agreed about the final disposition of the manuscript. But no one cited plausibility or lack of new results as reasons for rejection. In fact, most cited poor presentation or inadequacies in the methods as the rejection criteria. Douglas P.

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Peters and Stephen J. Ceci, *Peer-review Practices of Psychological Journals: The Fate of Published Articles, Submitted Again*, 5 BEHAV. AND BRAIN SCI. 187 (1982). Similar criticisms were offered in the study by Garfunkel, et al., *supra*. Steven Harnad, editor of PEER COMMENTARY ON PEER REVIEW, concludes (referring to the work of Peters and Ceci) that: ". . . any reader who thought that science was a matter of consensus should emerge from [reading the work of Peters and Ceci] thoroughly disabused of that notion. And lest be inclined to conclude that this outcome may pertain to particularly controversial material . . . let him sample other [author's] treatments. . .; nowhere will he find much evidence of univocality in important current work." Stevan Harnad, ed., PEER COMMENTARY ON PEER REVIEW: A CASE STUDY IN SCIENTIFIC QUALITY CONTROL 2 (1982). In another test, four researchers sent the same articles submitted to the JOURNAL OF GENERAL INTERNAL MEDICINE to different sets of reviewers. One member of each team was told the name and institutional affiliation of the author, while the second reviewer received the information "blind," *i.e.*, without information about the author's name and institutional affiliation. The researchers found that the "blind" reviews judged the article to be of a higher quality (and more deserving of publication) than did those reviewers who knew the author's name and affiliations. Robert A. McNutt, Arthur T. Evans, Robert H. Fletcher, and Suzanne W. Fletcher, *The Effects of Blinding on the Quality of Peer Review*, 263 J. AM. MED. ASS'N 1371 (1990). *See* Ann C. Weller, *Editorial Peer Reviews in US Medical Journals*, 263 J. OF THE AMER. MED. ASS'N 1344, 1346 (1990) ("prestige of author or [affiliated] institution" influenced the decisions of a sample of medical peer review journals to publish from 30.5% to 50% of the time).

Another investigator reviewed prior work on bias in peer review journals and concluded that the final disposition of a manuscript is influenced by the general stance of the conclusions (positive or negative), the prior publication records of the author(s), and other factors unrelated or weakly related to the quality of the research. Kay Dickersin, *The Existence of Publication Bias and Risk Factors for its Occurrence*, 263 J. AM. MED. ASS'N 1385 (1990). Additional evidence of bias on the basis of the size and magnitude of the reported effect and the size of the samples used can be found in many other studies. *See, e.g.*, Michael Mahoney, *Publication Prejudices: An Experimental Study of Confirmatory Bias in the Peer Review System*, 1 COGN. THER. AND RES. 161 (1977); Ina Spiegel-Rosing, *Science Studies: Bibliometric and Content Analysis* 7 SOC. STUD. SCI. 97 (1977); T.D. Sterling, *Publication Decisions and their Possible Effects on Inferences Drawn from Tests of Significance – or Vice Versa*, 54 J. AM. STAT. ASSOC. 34 (1959); T.C. Chalmers, R.S. Koff, and G.F. Grady, *A Note on Fatality in Serum Hepatitis*, 49 GASTROENT. 22 (1965); B. Sommer, *The File Drawer Effect and Publication in Menstrual Cycle Research*, 11 PSYCH. WOM. Q. 233 (1987); Von Bakanic, Clark McPhail, and Rita Simon, *The Manuscript Review and Decision-making Process*, 52 AM. SOC. REV. 631 (1987);
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These anomalies raise a troublesome question: if eventual publication by a single journal betokens "general acceptance", as has been claimed, what is the significance of previous rejections, particularly multiple rejections? If, as seems plausible, the rejection of a paper by a majority of the journals to which the paper had been submitted demonstrates general rejection, how can the publication of that paper by a presumably lesser-ranked journal magically transform it into a generally accepted one?[21] The answer to this conundrum is that courts should not attach too much significance (let alone dispositive weight) to the bare fact of publication (or non-publication). Surely, scientists do not. As participants in the peer review system, they realize that there is no simple, easy, foolproof, mechanical way of determining what is true and valid. They make judgments based on many factors.

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and C.B. Begg, and J.A. Berlin, *Publication Bias and Dissemination of Clinical Research*, 81 J. NAT'L CANCER INST. 107 (1989). In a particularly interesting study, one researcher reviewed 107 clinical trials of new therapies published in 1984 and found a correlation between the source of the funding and the direction of the results: 89% of the studies funded by pharmaceutical companies favored the new treatment versus 64% for studies not funded by pharmaceutical companies. R.A. Davidson, *Sources of Funding and Outcome of Clinical Trials*, 1 J. Gen. Intern. Med. 155 (1986). *See generally*, Daryl E. Chubin, *A Soap Opera for Science*, 37 BIOSCIENCE 259 (April 1987); Rick Crandall, *Peer Review: Improving Editorial Procedures*, BIOSCIENCE 607 (Oct. 1986); Chubin and Hackett, *supra*, at 8, 11-12, 94-103.

[21] The fallaciousnes of the argument that publication by one science peer review journal is tantamount to "general acceptance" by the entire scientific community, is best demonstrated by an analogy to the law. Imagine a litigant who won a favorable opinion from a single three-judge panel and then tried to stretch that isolated victory into a claim that his views were generally accepted by the entire legal community. If there were no other cases on point, the litigant might face no sanction harsher than being laughed out of court. If, on the other hand, his views had been presented to a number of courts of equal rank and, upon due consideration by those referees, had been rejected by each of those courts save one, a litigant's protestation that that a single acceptance somehow trumped all prior rejections might lead to sanctions a good bit more severe than derision. Similarly, one might reasonably wonder about the sense of a political candidate who insisted that victory in a single primary or endorsement by a single small-town paper constituted general acceptance by the entire electorate. Indeed, to state the proposition is to refute it.

They have few, if any, bright-line rules. In assessing the validity, or truth, or usefulness of an idea or datum, they may look to see if the idea or datum was published. But they rarely stop there. Instead, typically, they will look to see where it was published, who wrote it, what are their credentials, and so forth. It appears to us that courts should do no less.

V. JUST AS THE MERE FACT OF PUBLICATION DOES NOT SIGNIFY "GENERAL ACCEPTANCE", THE FACT OF NON-PUBLICATION DOES NOT INDICATE THAT IDEAS AND INFORMATION HAVE BEEN "GENERALLY REJECTED" OR THAT THEY ARE NOT AND CANNOT BE "GENERALLY ACCEPTED"

Scientists write, and seek to publish, papers for many reasons apart from the undiluted desire to report their insights and discoveries to the world: to gain tenure, attain promotions, acquire fellowships, win awards and honors, obtain funding for new projects, and retain funding for existing ones. The same ends -- including the broadcasting of new findings, ideas, and innovations -- can be accomplished in a number of different ways, including, but not limited to publishing articles in peer review journals.

There are at least four other ways in which scientists can introduce new ideas and information without publishing in peer review journals, ways that may be as least as effective, as least as impressive, and as least as well-established, legitimate, and well-regarded as publishing articles in peer review journals. *First*, scientists frequently are invited to give addresses at seminars, conferences, and colloquia; the printed versions of these speeches are usually reprised in the printed proceedings or reports of those conferences.[22] Although the speeches are not formally peer

[22] Sometimes speeches, or their content, find their way into textbooks which, interestingly, are not formally peer reviewed. They are usually informally read by friends of the authors, who make suggestions and are acknowledged in the prefaces. Multi-author texts, which are common in the biomedical sciences, are overseen by one or more editors but these individuals cannot possibly be (continued...)

reviewed either before or after they are delivered, the fact the authors were selected by their peers as speakers serves much the same quality control function.[23] ***Second***, "electronic bulletin boards" similarly offer instant dissemination by the authors -- and, ofttimes, instant questioning and critiques by those scientists who regularly peruse these electronic colloquia.

Third, reports and studies generated by and for federal, state, and local governmental agencies (and proposals submitted to such agencies by researchers seeking grants) likewise provide a way for scientists to exchange ideas and information. As noted in the National Research Council's recent study on so-called "Gray Literature," ENVIRONMENTAL EPIDEMIOLOGY: HEALTH AND HAZARDS (1991), government agencies rely heavily, indeed, at times almost exclusively, on such reports, notwithstanding the fact that they are not published in peer review journals. ***Finally***, private industry, corporate research consortia, and independent think tanks correspondingly commission the same sort of reports and studies from both staff scientists and independent consultants and rely on them just as heavily as government agencies, despite the fact that, once again, these papers are not formally published in peer review journals.

Some of the reports thus generated, whomever the sponsor and whatever the forum, are "pure or basic science," in the sense that they have no immediate and specific application; these

[22](...continued)
sufficiently expert in all the areas discussed in the text and, thus, cannot exercise any penetrating review of each part.

[23] In fact, authors who present such papers may be prevented from publishing their papers in peer review journals because of professional jealousies between, for example, research foundations and peer review journals. Thus, on the one hand, powerful funding establishments, like the Howard Hughes Medical Institute or the Robert Wood Johnson Foundation, reprint papers presented at fora they sponsor in the newsletters or magazines they publish. This practice can have the effect of preventing the same paper (and, occasionally, even the sequelae written by the same presenter) from being published in a peer review journal because some peer review journals, such as the NEW ENGLAND JOURNAL OF MEDICINE adamantly refuse to publish reports that first saw the light of day anywhere else -- be it at a public seminar, a private roundtable, or a televised news conference.

scholarly reports most closely approximate the pristine studies that are the ideal of peer review journals. Other studies and reports may lie closer to opposite extreme of "applied science," that is, utilitarian accounts that are generated in response to particular technical questions or specific technological or biomedical problems -- such as queries about the safety of a bridge design, evaluations of best location of a gas tank in a new car, predictions of how a new airport would affect highway traffic, or estimations of the side-effects of a new pharmaceuticals.

Perhaps the paradigmatic examples of high quality science that is almost never published are medical evaluations of particular patients with a specific disease. In such a situation, the questions are distinctively practical ones -- whether, for example, to treat a malignancy with radiation or chemotherapy. Yet, whether the work undertaken yields a new, theoretical advance in basic science or results in new, practical applications of venerable principles and regardless of whether the ideas are presented in a seminar or dictated into surgical notes, scientists will assess them on the basis of what they say and how they say it and how useful they are, and not on where and whether they were peer reviewed ahead of time. The fact remains that some of the best science is the most specific science. Most importantly, this sort of science may not be publishable not because it is wrong, or outside the mainstream of generally accepted views, but simply because a peer review journal editor might decide that it would not be of sufficient interest to enough of her subscribers.[24]

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[24] Nevertheless, even if an author aimed to publish the results of his or her research in a peer review journal and even if the none of impediments identified above barred his way, others barriers might. ***First***, a paper topic might be preempted by a virtually identical paper written by a different author. (Anyone who has had the misfortune of having a law review note topic preempted in the same fashion might empathize with the frustration endured by the Johnny-come-lately). ***Second***, even if a paper topic is not preempted, the author's time might be -- by anything from the exigencies of a personal crisis or a career move to being pulled from one topic to another, either by the entreaties of one's superiors or the lure of an intrinsically more interesting area of research or both. Because academic promotion and tenure decisions are strongly influenced by "publication counts," faculty members who wish to advance in their profession often feel intense pressures to publish. Even so, on occasion, some good research goes

. (continued...)

To be sure, corporations, think tanks, and litigants who commission studies and reports all want reports that suit their needs -- and their wishes are often fulfilled. This seems unremarkable. For this reason, courts need be skeptical of reports that were prepared and paid for by the partisans to a dispute, whether that dispute involves a patent fight between two inventors, a contract dispute between two corporations, or, as in the case before the

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[24](...continued)
unsubmitted or unpublished because graduate students and postdoctoral fellows (who take on a disproportionate share of the actual research) may leave for another school or lab before writing up their results. In other instances, research may go unpublished because the scientists get distracted by even more exciting discoveries (and the promise of more prestige or bigger research grants) and thus simply never get around to finishing old (and, by then, boring) manuscripts.

Competitive pressures may enter into decision of whether and when to publish in other ways. To cite but two examples, a researcher who learns that a competitor is close to publishing results of comparable research experiments may hasten to send his own manuscript to the editors of various journals in order to head off his colleague and thus to seize from her both the glory and the accompanying riches. On the other hand, another researcher who learns that a competitor is struggling with balky equipment that the first researcher has mastered, may hesitate to publish his research for fear that his explanation of how he obtained his results will enable his competitor to correct her errors and catch up. ***See generally***, James Watson, THE DOUBLE HELIX (1977) (describing the hunt to discover DNA that led to author's Nobel Prize, his team's heated rivalry with Nobel laureate Linus Pauling, and the various stratagems they employed to throw Pauling off the trail.)

Third, there is the problem of bias: (1) bias against some authors and schools, *id.*; (2) bias in favor of other authors and other institutions, *id.*; (3) bias against negative results, Dickersin, *supra*; (4) bias against particular results, *see, e.g.*, Boyce Rensberger, "DNA 'Fingerprinting' Is Disputed," Washington Post, Dec. 20, 1991, at A3 and "***'Science' Editor Denies Yielding to FBI Pressure***," SCIENCE & GOVERNMENT REPORT, Feb. 15, 1992, at 1; (5) bias against truly innovative ideas, *see, e.g.*, ***"Science Beyond the Pale"***, 249 SCIENCE 14 (July 1990) and *see, generally*, Thomas S. Kuhn, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (2d ed. 1970); and (6) bias against nuts-and-bolts "clinical research," as opposed to more ethereal "theoretical research." As to the last point, one researcher studied patterns associated with the publication of the results of clinical trials and concluded that the full reporting of the results of clinical trials is very irregular. "Substantial numbers of clinical trials are never reported in print, and among those that are, many are not reported in sufficient detail to enable judgements to be made about the validity of their results." Ian Chalmers, ***Underreporting Research Is Scientific Misconduct***, 263 J. AM. MED. ASS'N 1405 (1990).

Court, a tort suit between the manufacturer and consumers of a product. Moreover, it should not matter whether the report was prepared on the eve of a trial or prepared years earlier, not in preparation for a specific case, but generally in anticipation of litigation. Thus, experts who rely on non-published materials and who otherwise display no independent cast of mind or scholarship should be subject to close questioning (just like other experts); they should not be barred outright from testifying, however, lest the Court be willing to write off as tainted and unreliable every study and report that has not been published in a peer review journal. Not only is the peer review system less reliable as a quality control system -- in publishing only the good and in weeding out all of the bad -- than is commonly thought, but the efficacy of cross-examination hardly suffers in comparison the peer review system. Indeed, as discussed below, cross-examination suffers not at all in comparison.

VI. THE PEER REVIEW SYSTEM IS NOT MORE RIGOROUS AND MORE RELIABLE THAN THE LEGAL SYSTEM'S USE OF CROSS-EXAMINATION

Some observers have advanced the notion that the peer review system is much more rigorous and thereby more likely to reveal truths and uncover falsehoods than cross-examination. As noted above, some of the amici have not only participated in the peer review system as authors, referees, and editors but have also observed the legal system at close range, most specifically as expert witnesses who have endured cross-examination at depositions and trial. To put it bluntly, those amici who have personal experience with both systems find the notion that peer review is more strenuous and exacting than cross-examination completely mistaken.

The myth that peer review journals provide rigorous scrutiny of submitted papers is largely based on the underlying fable that peer review editors and referees replicate the experiments and analyses discussed in those papers. As noted above, they do not. Indeed, the meager amount of time spent by unpaid volunteer referees in reviewing submitted manuscripts hardly allows for

painstaking replication or other forms of rigorous scrutiny. It is a little-known but well-established fact (ironically, well-established in the peer review literature) that the average time spent on a review ranges between "less than" 2.0 hours and 2.4 hours, depending on the study. *See* n. 11, *supra*.

By contrast, cross-examination often subjects a witness to scrutiny that is longer-lasting, more intensive in depth, and more extensive in the breadth of subjects examined. ***First***, there are rarely time limits placed on cross-examination itself (and as most expert witnesses will attest, they must spend at least as much time preparing their testimony and explaining what it is all about to the lawyers who have hired them as they do on the witness stand.) ***Second***, once on the witness stand, a witness may be obliged to endure a line-by-line exegesis of his article and asked to explain and defend every point. ***Third***, the questions asked on cross-examination are not mercifully limited to the specific parameters of the paper or report that is the foundation of the expert's conclusion; instead, almost anything the expert has done, said, or written is fair game. For example, on cross-examination an expert witness can be subject to close questioning not only on the basis of the specific sources of his or her testimony, but can be impeached by anything he or she had said or written that is potentially inconsistent. His or her motives and credentials can be scrutinized in ways unimaginable to peer review editors and referees. The peer review system has nothing comparable. All in all, whatever the pressures are generated by the peer review system, cross-examination is, quite literally, a far more trying experience.

It is not often that scientists, sociologists, and historians have occasion to comment on the virtues of the legal system. In this case, however, it seems that the Court should take to heart its own admonitions about the value of cross-examination:

> The opportunity for cross-examination . . . is critical for ensuring the integrity of the fact-finding process. Cross-examination is "the principal means by which the believability of a witness and the truth of his testimony are tested." Indeed, the Court has recognized that *cross-examination is the "'greatest legal engine ever invented for the discovery of truth.'"*

Kentucky v. Stinger, 482 U.S. 730, 736 (1987) (citations omitted; emphasis added).

CONCLUSION

For the reasons stated above, the *amici* respectfully urge the Court to reverse the judgment of the United States Court of Appeals for the Ninth Circuit in this matter.

Respectfully submitted,

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APPENDIX

DETAILED DESCRIPTION OF THE QUALIFICATIONS OF, AND POSITIONS HELD BY THE *AMICI CURIAE*

Daryl E. Chubin is Senior Associate in the Science, Education, and Transportation Program, Office of Technology Assessment (OTA), U.S. Congress, where he has worked since 1986. Prior to coming to the OTA, Chubin was a full professor in the School of Social Sciences at the Georgia Institute of Technology, where he directed that school's Masters Program in Technology and Science Policy. He previously taught at Cornell University and the University of Pennsylvania. He received his Ph.D. in sociology from Loyola University, Chicago, in 1973 and was elected a Fellow of the American Association for the Advancement of Science (AAAS) in 1990. He has consulted for various divisions of both the National Academy of Sciences and the National Institutes of Health, the AAAS, the National Research Council, the American Chemical Society, as well as several private corporations and a number of non-profit organizations. He currently serves in an editorial capacity for five peer review journals (including for SOCIAL STUDIES OF SCIENCE, SCIENCE AND PUBLIC POLICY, BIOSCIENCE, and SCIENCE, TECHNOLOGY & HUMAN AFFAIRS), has been published in numerous peer review journals (including the aforementioned journals as well as SCIENCE, THE SCIENTIST, and CHRONICLES OF HIGHER EDUCATION) and is also the author of studies and reports that have been presented at various academic colloquia. He is the author of five books (including THE CANCER MISSION: SOCIAL CONTEXTS OF BIOMEDICAL RESEARCH (1980, co-authored); INTERDISCIPLINARY ANALYSIS AND RESEARCH (1986, co-edited), and SCIENCE OFF THE PEDESTAL: SOCIAL PERSPECTIVES ON SCIENCE AND TECHNOLOGY (1989, co-edited)). His most recent book, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY (1990), which he co-authored

with fellow amicus Edward J. Hackett, has been hailed as the most definitive book on the peer review system.

Edward J. Hackett is an Associate Professor in the Department of Science and Technology Studies at the Rensselaer Polytechnic Institute, where he has taught since 1984. He received his Ph.D in sociology from Cornell University in 1979. Among his many honors, he received a Postdoctoral Fellowship from the National Institutes for Mental Health. He has served as a book review editor for SCIENCE, TECHNOLOGY & HUMAN VALUES (STHV), and as a peer review referee for eight other journals, as well as a reviewer for the National Science Foundation (NSF) and as a member of grants peer review panels for the National Endowment for the Humanities. He has served as a speaker on NSF and AAAS programs and is the author of nine published articles. He is the coauthor, along with fellow amicus Daryl J. Chubin, of PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY (1990), which has been hailed as the most definitive book on the subject.

David Michael Ozonoff is presently the Chair of the Department of Environmental Health at the Boston University School of Public Health and Professor of Public Health as well as a Professor in the Department of Socio-Medical Science and Community Medicine at the Boston University School of Medicine. He has also lectured at, and directed the Concourse Program in the Department of the Humanities at, the Massachusetts Institute for Technology (MIT), worked as a Research Associate in the Department of History of Science at Harvard University, and served in the Office of Science and Technology at the World Health Organization. Dr. Ozonoff has served as an member of, or adviser to, various governmental bodies including the U.S. Department of Health and Human Services, the U.S. Environmental Protection Agency, the National Academy of Sciences, the

National Research Council, the U.S. Congress' Office of Technology Assessment, the Government Accounting Office, the Massachusetts Department of Public Health, the Massachusetts Department of Environmental Quality Engineering, the City of Boston's Department of Health and Hospitals, and the Boston School Department. He has additionally served as a consult to number private corporations and research establishments. Dr. Ozonoff has contributed chapters and essays to seven books, including the TEXTBOOK OF INTERNAL MEDICINE AND PRIMARY CARE, J. Noble, ed. (1987); MOLECULAR DOSIMETRY AND HUMAN CANCER: ANALYTICAL, EPIDEMIOLOGICAL AND SOCIAL CONSIDERATIONS, J. Groopman and P. Skipper, eds., (1991); GENETIC ALCHEMY: A SOCIAL HISTORY OF THE RECOMBINANT DNA CONTROVERSY, S. Krimsky, ed. (1982); HAZARDOUS WASTE DISPOSAL: ASSESSING THE PROBLEM, J.H. Highland, ed. (1982); and GENETICS AND THE LAW, III, A. Milunsky and G. Annas, eds. (1985). He is the author of 67 other scholarly papers and reports, including articles published in the NEW ENGLAND JOURNAL OF MEDICINE, THE AMERICAN JOURNAL OF PUBLIC HEALTH, THE ENCYCLOPEDIA BRITANNICA HEALTH AND MEDICAL ANNUAL, THE INTERNATIONAL JOURNAL OF EPIDEMIOLOGY, TERATOGENESIS, CARCINOGENESIS, AND MUTAGENESIS, HEALTH PHYSICS, AND CANCER IMMUNOLOGY AND IMMUNOTHERAPY, THE INTERNATIONAL JOURNAL OF HEALTH SERVICES, THE AMERICAN JOURNAL OF FORENSIC MEDICINE AND PATHOLOGY, THE AMERICAN JOURNAL OF INDUSTRIAL MEDICINE, AND TECHNOLOGY REVIEW. He serves as a consulting editor for the AMERICAN JOURNAL OF EPIDEMIOLOGY as well as in the same editorial capacity for the ARCHIVES OF ENVIRONMENTAL HEALTH. He earned his M.D. from Cornell University Medical College in 1967 and his M.P.H. from the Johns Hopkins School of Hygiene and Public Health in 1968. He has received awards from MIT, Harvard University, the John Hopkins University, and the Lund Institute of Technology Finally, he has served as an expert witness, and has testified at trials and/or depositions in more than 100 cases.

Richard W. Clapp has served as the Director of the Center for Environmental Health Studies for John Snow, Inc. in Boston since 1989. From 1980 through 1989, he served as the Director of the Massachusetts Cancer Registry, a division of the Massachusetts Department of Health. He currently is also an Assistant Clinical Professor at Tufts University School of Medicine and an Adjunct Assistant Professor at Boston University School of Public Health. He received his M.P.H. from the Harvard School of Public Health in 1974 and his Sc.D. in Epidemiology from the Boston University School of Public Health in 1989. He is a member of the American Public Health Association, the American College of Epidemiology, the Society of Epidemiologic Research, and the International Society of Environmental Epidemiology. He has published articles in such peer review journals as Cancer, the International Journal of Epidemiology, and the Journal of the American Academy of Dermatology, as well as having presented papers to assemblages of the American Public Health Association and other scholarly organizations. He presently serves on the editorial advisory board of NEW SOLUTIONS: A JOURNAL OF ENVIRONMENTAL AND OCCUPATIONAL HEALTH POLICY JOURNAL. He has also given testimony at numerous trials and depositions.

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Supreme Court of the United States

October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT,
Individually And As Guardians Ad Litem For
JASON DAUBERT, and ANITA DE YOUNG, Individually
And As Guardian Ad Litem For ERIC SCHULLER
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.
Respondent.

**On Writ Of Certiorari To The
United States Court Of Appeals For The Ninth Circuit**

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INTEREST OF AMICI CURIAE[1/]

Amici, scientists and organizations of scientists, lawyers and others with expertise on the use of scientific information in legal proceedings, file this brief amicus curiae with the consent of the parties as provided in the Rules of this Court.[2/] We write not to express a view on the controversy over whether Bendectin causes birth defects, but because we believe that, as a general matter, scientists' ability to be of assistance to judges and juries in determining a wide range of issues is threatened by the opinions of the lower courts in this case. Those holdings, if affirmed, pose a grave danger to the incorporation of valid and reliable scientific research in determining various factual issues that arise in litigation, and as such would cripple scientists in providing a meaningful contribution to the judicial process, and courts and juries in making meaningful determinations about issues requiring scientific expertise.

INTRODUCTION AND SUMMARY OF ARGUMENT

This Brief assumes that, for reasons recounted in the Brief for Petitioner, the rule of admissibility derived from Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), did not survive the promulgation of the Federal Rules of Evidence, and that it is those rules, standing alone, that govern the admissibility of expert scientific evidence in federal courts.

I. We begin by noting that there has been a tendency in making evidentiary rulings about expert scientific evidence first, to confuse questions of admissibility with issues pertaining to sufficiency of the evidence, and second, to seek per se evidentiary rules rather than contextual ones -- that is, principles that turn admissibility upon the purpose for which the expert evidence is sought to be introduced in the particular case, and upon the nature of the opposing evidence.

[1/] All parties have consented to the submission of this brief.

[2/] Statements of interest of each amicus appears in an Appendix to this brief.

For reasons we discuss in Part I, infra, there is a wide range of circumstance for which expert scientific evidence may be appropriate in court cases (and in those agency proceedings that apply the Federal Rules of Evidence), of which the present toxic tort causation context is only one. Any approach that regards particular kinds of evidence -- for example, animal studies, chemical analyses, or studies not published in peer reviewed journals -- as per se inadmissible with regard to human injury or harm is, as we show, likely to hamper severely the contribution of scientists to the truth-finding process that is at the heart of the judicial process.

II. In this case, the court below concluded that the methodology of plaintiff's scientists' studies was "problematic" — and therefore per se inadmissible — simply because their analyses relied upon kinds of scientific evidence other than human epidemiological studies that had been published in peer-reviewed journals.

As we show in Part II, infra, however, the methodologies used by the rejected experts (as opposed to their conclusions using those methodologies, which we do not attempt to judge) are routinely used by practicing scientists, both in the private sector and throughout government, to identify substances likely to cause human injuries. Indeed, the federal government sanctions those same methods to determine in the regulatory process the safety of food additives, drugs, cosmetics, medical devices, industrial chemicals, pesticides, and a wide range of other potentially toxic substances, and has published extensive protocols governing the conduct and interpretation of those methodologies. In those protocols, in vitro studies (laboratory studies of biochemical processes), in vivo studies (animal studies), and epidemiological studies are all expressly recognized as useful in predicting the effect of various substances on humans, and research conducted especially for the particular regulatory purpose, and not published in any peer-reviewed journal, is routinely relied upon to determine the safety of various products and processes.

It is true that the purposes and processes of regulatory agency proceedings, aimed at prospective risk elimination, differ sufficiently from retrospective jury damages trials and that the same

evidentiary standards would not apply. Nonetheless, the widespread use in regulatory proceedings of the very kinds of evidence excluded automatically here indicates scientists' reliance on those types of evidence to determine the cause of human injuries. As such, there is no basis for the per se exclusion of such evidence sanctioned by the Ninth Circuit.

ARGUMENT

I. THE LOWER COURT'S PER SE RULE EXCLUDING VALID AND RELIABLE EVIDENCE VIOLATES SCIENTIFIC PRINCIPLES AND IS INCONSISTENT WITH THE PURPOSE OF THE RULES OF EVIDENCE.

A central purpose of the Federal Rules of Evidence is to enable the fact-finder to make the most informed decision possible. The Rules accomplish this end, in part, by providing for testimony by qualified experts who possess "scientific, technical or other specialized knowledge." Fed. R. Evid. 702.

In particular, Rule 702 focusses upon whether or not expert evidence will "assist the trier of fact", which assumes that the evidence is based upon scientifically recognized and defensible methods; Rule 703 requires that the facts and data used (as opposed to the methods of evaluating that data) be "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences"; and Rule 403 permits exclusion of otherwise admissible evidence, including expert evidence, where the evidence's probative value is outweighed by a "substantial danger of unfair prejudice, confusion of the issues, or misleading the jury."

(a) Rules 702 and 403 are thus "contextual" rules, turning admissibility at least in part upon the precise nature of the pertinent issues, the applicable standard of proof, and the other evidence in the case. A determination whether expert evidence will be of assistance to the trier of fact or, instead, is more likely to mislead the jury thus depends on the purpose for which it is being offered -- for example, whether the evidence is being introduced to prove

causation in a products liability case, or, instead, to help establish a different cause of action, with different elements.

Thus, in a constitutional libel case, parties may seek to introduce scientific evidence supporting the truth of a published assertion to demonstrate absence of "malice" or lack of reckless disregard for the truth. The truth or falsity of the scientific assertion in such a case may be less important than whether the party's reliance on it was reasonable.

Similarly, the parties in an age discrimination case may introduce expert scientific evidence regarding the validity of an employer's medical policy or benefit plan, in an effort to prove discriminatory intent. And parties bringing "citizen suits" in the federal courts to obtain injunctive relief for alleged violations of the federal Clean Water Act, Clean Air Act, the National Environmental Policy Act and similar statutes rely on scientific evidence from the frontiers of science to prove that an enterprise threatens human health or the environment. Davis, The "Shotgun Wedding" of Science and Law: Risk Assessment and Judicial Review, 10 Colum. J. Envtl. L. 67 (1985); J. Bonine & T. McGarrity, The Law of Environmental Protection, pp. 797-815, 861-866 (2d ed. 1991), and see, e.g., Natural Resources Defense Council v. Texaco Refining & Marketing, 800 F.Supp. 1, 7, n.2 (D.Del. 1992). Where the question is whether someone reasonably believed something to be true, or whether an impermissible motive precipitated certain acts, or whether there is a risk of harm from a particular chemical exposure, the range of relevant, admissible scientific evidence might, under Rules 702 and 403, be broader than where the issue is one of actual causation related to a particular individual's injury.

Similarly, some kinds evidence could be helpful, and not unduly prejudicial, when there is no other kind of evidence available because of the practicalities of certain kinds of scientific research, see Part II, infra, but it would not be helpful and might be misleading where more direct evidence is readily available but has not been produced.

(b) Rule 702, however, also arguably involves a per se element, insofar as it is read to incorporate into the "assist the trier

of fact" standard some judicial ability to assure use of responsible scientific methodology. And Rule 703 suspends the hearsay rule on an objective, per se basis, unrelated to the issues, standard of proof, or opposing evidence in the particular case.[3]

There is no basis in the language of either Rule 702 or Rule 703, however, for erecting a per se standard of admissibility stricter than the standard used by scientists themselves in determining whether a study sufficiently partakes of the attributes of scientific research to be regarded as probative by scientists in the relevant field. And, to working scientists, the credibility or value of a scientific approach or opinion depends more on the strength of the factual premises, on the compatibility with other known facts, and on the methodology and reasoning, than the number of scientists who agree with the result or the fact that the contrary opinion can also be supported by reference to respectable scientific research.

To comport with this fundamental aspect of the scientific process, the evidentiary rules must be interpreted flexibly enough to permit the introduction of scientific opinions and evidence from qualified experts based on what they reasonably believe is valid and reliable. The decision on whether or not to submit a particular study or data to peer review for publication often turns on factors entirely unrelated to the scientific validity or value of the evidence at issue. And expert opinions may address areas in which little direct empirical research has been done because of the novelty of the problem; or may represent a respectable but minority view among scientists; or may be based on the use of established

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[3] There is a debate in the case law, which we do not address, concerning whether or not Rule 703 applies the "reasonably relied upon by experts in the particular field" standard only to the raw data relied upon, or also to the interpretation of that data. See, e.g., Christopherson v. Allied-Signal Corp., 939 F.2d 1106, 1114, 1118-20 (5th Cir. 1991); (Clark, J., concurring in the result), cert. denied, ___ U.S. ___, 112 S.Ct 1280 (1992). For present purposes, it suffices to note that there is some objective, non-contextual review appropriate under Rule 703, at least insofar as expert testimony relies on hearsay.

methodologies upon data collected or aggregated in innovative ways; or may constitute critiques of the existing body of research on bases appropriate in reviewing scientific studies.

In any of these circumstances, per se exclusion of the informed opinions of qualified scientific experts, for example because the underlying studies relied upon have important limitations or are not published in peer-reviewed scientific journals, would leave the judicial process the poorer. Such automatic exclusion, instead, should be reserved for circumstances in which the basic methodology (not the ultimate conclusions) of the research relied upon is simply outside the realm of scientific respectability.

We are not suggesting that the opinion evidence of plaintiffs' experts in this case properly could or should have been excluded even under the contextual standards for expert testimony, as insufficiently helpful concerning the causation issue, or as too misleading given its probative value. Rather, our point is more general: There may be circumstances in which scientific evidence could be excluded on these bases, taking into account the elements of the cause of action, the opposing expert evidence, and the practical reasons why the particular type of scientific evidence is being offered as opposed to some other type. And since such contextual weighing is available under the Federal Rules, it is to be preferred over a more automatic approach, which will only lead to mandatory ignorance in the courtroom, and poorer judge and jury decisionmaking in a wide variety of circumstances.

(c) The history of Bendectin litigation in various courts illustrates another reason why automatic exclusion of scientific evidence should be confined to extreme situations of breach of basic standards of scientific method: While some courts, like the Ninth Circuit in this case, have excluded entirely from evidence any expert testimony based upon non-epidemiological studies and studies not published in peer-reviewed journals, other appellate courts have precluded judgment for plaintiffs on the basis that those same kinds of evidence, while admissible, are insufficient to sustain a verdict for the plaintiff. Compare Lynch v. Merrell-National Laboratories, 830 F.2d 1190 (1st Cir. 1987); Richardson v. Richardson-Merrell Inc., 857 F.2d 823 (D.C. Cir. 1988), cert. denied, 493 U.S. 882

(1989) with Brock v. Merrell Dow Pharmaceuticals, 874 F.2d 307, modified, 884 F.2d 166 (5th Cir. 1989), cert. denied, 494 U.S. 1046 (1990). As the Third Circuit noted in DeLuca v. Merrell Dow Pharmaceuticals, 911 F.2d 941, 958-59 (3rd Cir. 1990), the conclusion that in some circumstances a case may be appropriate for summary judgment, or for a directed verdict, even though there is some admissible expert evidence supporting plaintiff's theory of causation, relates to the applicable burden of persuasion: Even if disputed expert testimony is admissible, that testimony "may be found sufficiently helpful to support a jury finding that Bendectin can cause birth defects or even that Bendectin not infrequently causes birth defects", but still would not bar summary judgment for defendants "unless it would support a jury finding that Bendectin more likely than not caused the birth defects in this particular case."[4] In other words, the expert evidence may be sufficient to prove some increased risk of a particular harm due to exposure to a particular substance, but not to exclude as more probable the conclusion that other causes are responsible.[5]

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[4] We note that, as the DeLuca court stated, sufficiency of the evidence would, in a toxic tort case such as this one, necessarily be tested against the burden of proof standard under applicable state law. 911 F.2d at 958-59.

[5] For example, the expert evidence might show that it is ten percent more likely that a person exposed to a particular substance will get cancer than one who is not so exposed, while indicating at the same time that ninety percent of the people who get the same form of cancer have no such exposure, and must have gotten the cancer from some other, unknown source. Under those circumstances, it is arguable whether summary judgment might be appropriate in a toxic tort context because there is no evidence indicating that it is more probable that the particular case of cancer in question was caused by the putative exposure than by one of the unknown causes.

We note that the very same expert evidence would, however, almost surely support a regulatory or judicial finding that the substance in question presents an unreasonable risk to human

(continued...)

We take no position on the propriety of summary judgment or a directed verdict on this record or on the record in any of the other Bendectin cases. What conclusion might be reached if the courts below had considered all the valid and reliable research that has been conducted on Bendectin is impossible to predict. Admitting such testimony and evidence does not signify that it will be sufficient to meet the requisite burden of proof (or, if it is sufficient on its face to survive a motion for summary judgment, that plaintiff's experts rather than defendants will be credited by the jury after the rigors of cross-examination). Even if those hurdles are met, the plaintiff must still provide evidence sufficient to survive summary judgment on the additional elements of the cause of action in order to advance to trial.

The summary judgment approach, however, where proper on the evidence presented, is considerably more respectful of the uneasy interaction of science and law than total exclusion of expert testimony. By admitting the evidence and then testing it against the applicable burden of persuasion, courts can adjust directly for the differences between scientific and legal decision-making, rather than hiding that decision behind an evidentiary ruling. In doing so, courts can allow cases to go forward depending upon the precise elements of plaintiffs' cause of action and burden of proof, and a detailed consideration of plaintiffs' total evidence on the point for which expert evidence is introduced, rather than on each piece of evidence in isolation.

(d) Both the court of appeals and the trial court in this case, however, misinterpreted their proper role in ruling on the

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[9](...continued)
health and should be prospectively excluded from the market under a statute providing for exclusion on that standard. See also Part II, infra. The reason for the different results is that the substantive inquiries are fundamentally different where the question is causation of an individual injury, as opposed to assessment of the risk posed to the population as a whole. Any per se evidentiary approach, in contrast, would treat the two situations as equivalent, and exclude the expert evidence entirely in a court case in both circumstances.

admissibility of evidence. The trial court searched for a consensus in the scientific community by looking at how other courts disposed of similar claims on the merits. It thus discerned and relied on a "consensus" in the legal community, not the scientific community, on the ultimate question to be determined -- whether there is sufficient evidence of a causal link between Bendectin and certain birth defects to support a judgment for the plaintiffs, a process that merged evidentiary questions with the determination on the merits. This error was compounded by the fact that some of the courts included in this "consensus" had themselves excluded types of evidence that scientists normally rely on, especially animal and other experimental data, a determination the trial court specifically endorsed in holding that causation could only be demonstrated through epidemiological data.

The appellate court, similarly, sought to limit the admissibility of evidence to facts and opinions apparently consistent with the "consensus" on the merits of the causation issue in the case. By doing so, the Ninth Circuit likewise failed to separate evidentiary determinations from scientific methodology considerations, and methodological considerations from the conclusions that are drawn from the application of a particular methodology to properly collected data. Thus, the courts below both apparently sought to preclude litigation they viewed as repetitive on the ultimate causation questions by use of inappropriately restrictive evidentiary rulings.

What is clear, however, is that a scientific consensus exists that in order to determine the ultimate questions of risk and causation, all methodologically valid and reliable sources of data and analysis of data must be evaluated. This the courts below failed to do. The exclusion of scientifically relevant information from consideration violates both legal and scientific norms and, unless corrected by this Court, will predictably distort the legal fact-finding process.

II. EXCLUSION OF EXPERIMENTAL STUDIES AND STUDIES NOT PUBLISHED IN PEER-REVIEWED JOURNALS CONTRAVENES STANDARD SCIENTIFIC PRACTICE AS EXEMPLIFIED IN FEDERAL REGULATORY PRACTICES.

Instead of permitting an evaluation of valid and reliable data from the sources that scientists normally use, the courts below, and other courts they cite, irrationally and artificially limited the universe of relevant facts. Those courts concluded that the apparently negative epidemiological data could not be rebutted by experimental data, and that only positive epidemiological studies published in peer-reviewed journals could suffice to prove causation.

The question then becomes whether scientific opinion concerning causation of human harm is, as a general matter, outside the realm of scientific respectability unless based on human epidemiological studies published in peer-reviewed journals. Otherwise, the decision below was incorrect, and should be reversed. One need look no further than the practices of numerous federal agencies staffed by experienced and respected scientists to discover that the courts below were simply wrong in so narrowly restricting the realm of scientific information useful in coming to an informed conclusion on a causation issue such as the one in this case.

(a) A rule in cases involving toxic substances limiting admissibility to peer-reviewed human epidemiological studies misapprehends, first, the nature of scientific inquiry into causation, and the nature and limitations of epidemiology. Data from well-designed and well-conducted human epidemiology may be a highly desirable form of data, but many factors preclude that methodology from being the sole or principal authority upon which courts should rely in determining causation of human harm generally, or in assessing reproductive and developmental risk particularly. And although experimental data have drawbacks that may sometimes limit their usefulness in assessing human risk and causation issues, similar methodological difficulties apply to epidemiology as well. These considerations, however, do not preclude scientists from

making valid conclusions about causation in appropriate circumstances.

(1) First, as evidenced in virtually all federal regulations dealing with toxic risk assessments, experimental data based on studies of animals are a critical element of the process of assessing the nature and extent of health risk associated with chemical and other exposures and in evaluating the causal relationship between such exposures and certain adverse outcomes, including but not limited to birth defects and other developmental and reproductive effects.

For example, the Environmental Protection Agency ("EPA"), the federal agency charged with enforcement of the nation's most comprehensive public safety and health statutes, and with the overall regulation of toxic substances, recently issued Final Guidelines for Developmental Toxicity Risk Assessment ("Guidelines"), 56 Fed. Reg. 63798 (1991). The Guidelines resulted from extended regulatory proceedings in which both agency scientists and members of the relevant scientific community participate, and were issued after public notice and an opportunity to comment. As such, they represent a close approximation of a "consensus" approach to an inquiry into appropriate research methods for discovering the cause of adverse developmental outcomes.

The Guidelines restate a fundamental scientific premise, ignored in the evidentiary rulings in this case:

> Hazard identification/dose-response evaluation involves examining all available experimental animal and human data and the associated doses, routes, timing and duration of exposures to determine if an agent causes developmental toxicity....

Id. at 63799 (emphasis added). Moreover, the significance of animal data in assessing human reproductive risk is specifically noted:

> [I]t is assumed that an agent that produces an adverse developmental effect in experimental animal studies will potentially pose a hazard to humans following sufficient exposure during development ... . [I]n almost all cases, experimental animal data are predictive of a developmental effect in humans.

Id. at 63801.

Similarly, in the detection of agents capable of altering genetic material in sperm or ova (mutagens), creating a risk of heritable or transmissible injury to future generations after exposure of either parent, EPA has determined that it is "appropriate to rely on data from experimental animal systems...."[9] See also Environmental Protection Agency, Proposed Guidelines for Assessing Female Reproductive Risk, 53 Fed. Reg. 24834, 24836 (1988) (reiterating the need for reliance on "evaluation of toxicological data from humans and experimental animals..." in making reproductive and developmental risk assessments)(emphasis added); Occupational Safety and Health Administration, Final Standard for Occupational Exposure to Ethylene Oxide, 49 Fed. Reg. 25734, 25743-4 (1984)(describing the agency's "comprehensive review of the scientific evidence... from many investigations in several species of experimental animals ...as well as positive results from several human studies," and noting that a rat study "provided the strongest evidence" of the carcinogenic properties of EtO.).

The significance of experimental data is further acknowledged by the multi-billion dollar research investment funded over the last 40 years by the National Institutes of Health. The majority of that funding has gone to support bio-medical research using experimental models. See, e.g., T.J. Gill, et al., The Rat As An Experimental Animal, 245 Science 269 (1989). Nobel Prizes in physiology and medicine have frequently been awarded for research using experimental animals. See 8 Encyclopedia Britannica 740-47

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[9] Environmental Protection Agency, Guidelines for Mutagenicity Risk Assessment, 51 Fed.Reg. 34006, 34008 (1986).

(1991). Our understanding of genetics and molecular biology began with research on fruit flies and worms in the 1920s, and this research formed the basis for the identification of major human diseases. J.D. Watson, et al., Molecular Biology of the Gene (4th ed. 1987). These sources only begin to suggest the fundamental nature that experimental data play in shaping scientific knowledge and opinion. See also National Academy of Sciences, National Research Council, Biological Markers in Reproductive Toxicology (1989); National Academy of Sciences, Principles for Evaluating Chemicals in the Environment (1975).[7]

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[7] A partial list of federal laws, regulations and standards in which animal studies are used to assess human health risks includes: the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-137, and accompanying regulations, e.g., 40 C.F.R. § 154.7(a)(2)(i); Federal Food, Drug and Cosmetic Act, 11 U.S.C. § 348(c)(3)(A) ("no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal"); the Consumer Product Safety Act, 15 U.S.C. § 2079(a) and the Federal Hazardous Substances Act § 2(f)(1)(A), 15 U.S.C. §§ 1261, 1262, and accompanying regulations, e.g., 16 C.F.R. § 1500.17(a)(10), and 43 Fed. Reg. 12308-12310 (animal studies are the basis for classification as banned hazardous substances of self-pressurized household substances containing vinyl chloride monomer); Safe Drinking Water Act, 42 U.S.C. §§ 300(f), et seq., and accompanying regulations, e.g., 44 Fed. Reg. 68624, 27; Toxic Substances Control Act, 15 U.S.C. §§ 2601-2629 (1976), especially §2603(b)(2)(A) (providing for "standards for the development of test data", including "epidemiological studies, serial or hierarchical test, in vitro tests, and whole animal tests," emphasis supplied); Federal Water Pollution Control Act, § 307(a), 33 U.S.C. § 1317(a) (1976), and accompanying regulations, e.g., 41 Fed. Reg. 30476-77 (1976) and 42 Fed. Reg. 6532 (1977) (proposed and final discarges standards for PCBs based on evidence of animal carcinogenicity); Federal Clean Air Act, 42 U.S.C. § 7412, and accompanying regulations, e.g., National Emission Standards for Hazardous Air Pollutants: Proposed Standard for Vinyl Chloride, 40 Fed. Reg. 69532 (December 24, 1975) (rationale for the standard includes

(continued...)

Thus, there are both clear standards for "good" experimental science and accepted principles governing the applicability of such data to humans.

(2) The basis for consensus as to the importance of experimental data is not only that such data are crucial to an understanding of the mechanisms of causation of human injury, but also that human epidemiology is for various reasons intrinsically limited in this respect. Together the two forms of investigation provide complementary information that can lead to a much fuller understanding of risk and causation than either, separately, permits.

First, "[e]pidemiological studies are inherently capable of detecting only comparatively large increases in the relative risk....Negative results cannot prove the absence of [risk]...." EPA Final Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33992, 33995-96 (1986).

Thus, positive epidemiological study establishes a statistical probability that a particular agent causes a particular effect. And, of greater import in this case, because of the heavy reliance placed by the lower courts on the negative epidemiological data, is the fact

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[2](...continued)
animal test data demonstrating carcinogenicity of vinyl chloride as well as epidemiological studies); Occupational Safety and Health Act, 29 U.S.C. § 655, and standards issued thereunder, e.g., OSHA Cancer Policy, 29 C.F.R. § 1990.111(a), relying on positive results in high-dosage animal tests "to establish the qualitative inference of carcinogenic hazard to workers", and 39 Fed. Reg. 35890, 35891 (1974), 38 Fed. Reg. 10929 (1973) (OSHA exposure standards for vinyl chloride and ethyleneimine, respectively, based on animal studies indicative of carcinogenicity); and the Resource Conservation and Recovery Act, 42 U.S.C. § 6901 et seq., especially 42 U.S.C. § 6421 and implementing regulations at 40 C.F.R. § 261.11(a) (including as a hazardous waste substances that "have been shown in scientific studies to have toxic, carcinogenic, mutgenic or teratogenic effects on humans or other life forms." (emphasis supplied)).

that the absence of a statistically significant relationship in a particular study does not necessarily signify the absence of a cause and effect relationship:

> A high-quality negative epidemiological study, while useful, cannot prove the absence of an association....

Office of Science and Technology Policy, Chemical Carcinogens: A Review of the Science and its Associated Principles, 50 Fed. Reg. 10372, 10378 (1985); see also EPA Final Guidelines for Carcinogen Risk Assessment, supra, 51 Fed. Reg. 33995 (human epidemiology "can rarely be used to make a causal inference").

The failure to discover a statistically significant relationship between a particular exposure and effect may occur because the effect does not exist, or it may occur because the study has too few subjects, failed to control for confounding variables, or for other reasons. Experimental studies demonstrating a biologically plausible mechanism by which injury could occur and the existence of such an effect in other species or test systems are an essential aspect of the inquiry into causation, because they can explain what has been observed through epidemiological inquiries. See E.K. Silbergeld, The Role of Toxicology in Causation: A Scientific Perspective, 1 Courts, Health Science & the Law 374, 381 (1991) ("[n]otions of cause in science involve knowledge of mechanism. They go beyond the accumulation of linked observations...."); see also A.S. Evans, Causation & Disease, 49 Yale J. Biol. & Med. 175 (1976).

Retrospective studies relying on individuals' accounts or on medical records that may be incomplete or inaccurate may be unreliable. Because epidemiology confirms past harms, experimental methods which seek to predict and avoid such harms have obvious advantages. D.L. Davis, Changing Policy Rules of Environmental Epidemiology, 3 Statistical Science 281 (1988).

Furthermore, as a practical matter,

> [r]eliable epidemiologic data on long-term human risks cannot exist for recently introduced toxic

> substances and is rarely available for chemicals in longstanding use. Thus, most attempts to regulate toxic hazards must rely on extrapolation of human risks from animal test data.

Latin, Good Science, Bad Regulation, and Toxic Risk Assessment, 5 Yale J. Reg. 89, 103 (1988).

One reason that it is difficult to obtain epidemiologic data is that for such studies large populations need to be studied over an extensive time period; cancer may take decades to develop, while some heritable disorders may only be observable after two or more generations. Reliance on experimental data avoids some of these problems and, in addition, is justified because "chemicals causing genetic effects in one species or test system frequently cause similar effects in other species or systems." 51 Fed. Reg. 34008.

In short, all forms of scientific data are subject to criticism on one methodological ground or other,[#] but that does not preclude valid judgments and determinations regarding causation if the various approaches are used with an understanding of their power and their limitations. The response of regulatory agencies has been consistent in their reliance on all sources of information where data have been generated through accepted scientific methodology and according to good scientific practice. By directly and indirectly excluding information that regulatory agencies and

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[#] The limitations of epidemiology are apparent from the foregoing discussion. Indeed, if plaintiffs here had relied on epidemiological data, there is little doubt that the defendants would have challenged that data as insufficient methodologically. The history of regulatory proceedings assessing the risks of toxic exposures demonstrates that questions have been raised about the validity and pertinence of data of all sorts, including published, peer-reviewed, epidemiological data. See, e.g., Attachments to the Preamble for the Final Standard for Occupational Exposure to Lead, 43 Fed. Reg. 54353 - 54509 (1978); Occupational Safety and Health Administration, Final Standard for Occupational Exposure to Ethylene Oxide, 49 Fed. Reg. 25734, 25739 (1984).

most practicing scientists deem essential in determining risk and causation issues, the courts below have adopted an indefensible view of what counts in scientific inquiry.

(b) Similarly, by excluding all scientific evidence not published in peer-reviewed journals, the courts below barred from legal consideration a wide range of scientific material upon which scientists as well as policy makers routinely rely. Indeed, a massive amount of valid and rigorous scientific data is not published in peer-reviewed journals, and would be excluded under the standard applied below.

The best illustration that scientific evidence can be reasonably relied upon by experts in the field, even if it has not appeared in a peer-reviewed journal, can be seen in the working of the federal agency created to test the safety of chemicals. The National Toxicology Program (NTP) was established in 1978 by the Secretary of the then Department of Health, Education and Welfare to test chemicals for their health effects and to develop and validate improved test methods. NTP routinely conducts experimental studies to determine whether substances are carcinogenic or have other adverse health effects. The results of these studies are issued directly by NTP in the form of a Technical Report.

As of July 1992, NTP had issued four hundred sixteen Long Term Technical Reports and Short Term Toxicity Study Reports for hundreds of chemicals. These Technical Reports are widely relied upon by state and federal agencies for a host of decisions on regulating toxic substances, resolving disputes between conflicting studies, and similar purposes[#].

It would be inappropriate for two reasons to publish the results of an NTP cancer study in a peer-reviewed journal.

[#] NTP employs an external scientific review process to insure the integrity of its research, but results are not published in a peer-reviewed journal and would not meet the per se standard adopted by the Ninth Circuit in this case.

First, if the NTP determines that a substance is carcinogenic, withholding the release of the study results pending acceptance in a peer-reviewed journal would delay the initiation of the appropriate regulatory process to consider how to protect the public. In fact, NTP anticipated this kind of situation and established a procedure whereby, if preliminary evidence suggests that a chemical is highly carcinogenic, federal regulatory agencies, manufacturers, trade associations, labor unions, public interest groups, and others are affirmatively notified even before the Technical Report is completed. To await the completion of a journal's peer review process could unnecessarily prolong the public's exposure to a harmful substance.

Second, the vast majority of the studies used to evaluate the health effects of chemicals are conducted using widely accepted and very explicit scientific protocols. Because these protocols have become so commonplace, the studies are not likely material for journals that necessarily must seek research on new scientific methods. This absence of peer review, however, has no bearing whatsoever on the scientific quality or probative value of NTP Technical Reports or their acceptance in the scientific community.

Moreover, data not published in peer-reviewed journals are commonly used for many other varieties of scientific and regulatory purposes. Under a broad array of federal statutes, including the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), The Federal Food, Drug and Cosmetic Act (FFDCA), the Toxic Substances Control Act (TSCA), and others, manufacturers are required to test their compounds for health and environmental effects as a condition for receiving government approval for sale and use. Generally, these studies, conducted in accordance with standardized test procedures in order to ensure their validity, are submitted to the appropriate federal government to determine how the compounds should be regulated.

For example, FIFRA requires that all pesticides sold or distributed in the United States must be registered by the U.S. Environmental Protection Agency. FIFRA § 3(a), 7 U.S.C. § 136(a). Such data are used to determine whether the statutory standard for registration has been met, i.e., that a pesticide "when

used in accordance with widespread and commonly recognized practice ... will not generally cause unreasonable adverse effects on the environment." FIFRA § 3(c)(50(D), 7 U.S.C., § 136a(c)(5)(D).

EPA publishes detailed guidelines specifying the type of data necessary to support a pesticide registration. FIFRA § 3(c)(2), 7 U.S.C. § 136a(C)(2). The regulatory guidelines, and the underlying Pesticide Assessment Guidelines and Standard Laboratory Practices, explicate requirements for over a hundred different studies on the health and environmental effects of individual pesticides. Yet nowhere in the federal statute or the regulatory guidelines is it required that a study be published in a peer-reviewed journal as a precondition for consideration in EPA's pesticide registration decision. Rather, in its general policy regarding acceptability of data, the Agency will:

> determine whether the data submitted to fulfill the data requirements specified in this part are acceptable. This determination will be based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement. In evaluating experimental design, the Agency will consider whether generally accepted methods were used, sufficient numbers of measurements were made to achieve statistical reliability, and sufficient controls were built into all phases of the experiment. The Agency will evaluate the conduct of each experiment in terms of whether the study was conducted in conformance with the design, good laboratory practices were observed, and results were reproducible.

40 C.F.R. § 158.80 (1988).

To date, over six hundred pesticide active ingredients have been federally registered for use, largely on the basis of studies not published in peer-reviewed journals.[19]

Analogously, pursuant to Section 8(e) of the Toxic Substances Control Act, 15 U.S.C. § 2607(e), manufacturers must immediately disclose to EPA any adverse effects caused by their products. On September 15, 1992, for example, by letter IBM Corporation notified EPA under TSCA Section 8(e) that diethylene glycol dimethyl ether and ethylene glycol monoethyl ether acetate caused adverse reproductive effects, including increased spontaneous abortions. This disclosure was based on a preliminary, and yet unpublished, analysis of 1980-1989 data collected as part of an epidemiological study of IBM's semiconductor manufacturing employees and their work environment at two sites.

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[19] Similarly, Section 6 of FIFRA authorizes the Administrator to cancel or suspend pesticide registration if the product does not comply with FIFRA or generally causes unreasonable adverse effects on the environment. FIFRA § 6, 7 U.S.C. § 136d. The Administrator's cancellation or suspension decision is not limited to consideration of studies published in peer-reviewed journals. In fact, the statute requires pesticide registrants at any time to submit to EPA "additional factual information" regarding a pesticide's unreasonable adverse effects, a category clearly far broader than only information published in a peer-reviewed journal.

EPA routinely cancels or suspends pesticides on the basis of studies not published in peer-reviewed journals. For example, on October 7, 1986, EPA issued an emergency suspension of a widely used pesticide ingredient, dinoseb. The suspension order was based upon scientific data EPA summarized as demonstrating that "dinoseb is a developmental toxicant in laboratory animals." 51 Fed. Reg. 36636 (October 14, 1986). These data were unpublished studies submitted to EPA by dinoseb's manufacturers but deemed by the Agency to be scientifically valid and sufficient indicators of cause for concern to warrant suspension of the pesticide. See Love v. Thomas, 858 F.2d 1347 (9th Cir. 1988), cert. denied, 490 U.S. 1035 (1989).

(c) None of this is to say that the same ultimate evidentiary considerations apply in agency regulatory proceedings as in judicial jury trials concerning individual causation. Indeed, the Federal Rules of Evidence, as such, ordinarily do not apply in regulatory risk-assessment proceedings.

The Administrative Procedure Act provides that technical rules for the exclusion of evidence do not apply before federal agencies. Under the APA, "any oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence." 5 U.S.C. § 556(d).

Specific statutes, however, can override the application of the APA to agency hearings. In addition, agencies can voluntarily adopt their own evidentiary rules.

Upon enacting the APA, Congress codified case law establishing that exclusionary rules were inapplicable to agency proceedings. This Court stated in 1941 that "it has long been settled that the technical rules for the exclusion of evidence applicable in jury trials do not apply to proceedings before federal administrative agencies in the absence of a statutory requirement that such rules are to be observed." Opp Cotton Mills v. Administrator, 312 U.S. 126, 155 (1941).

In 1971, in Richardson v. Perales, 402 U.S. 389 (1971) the Court indicated that it favored a broad interpretation of agency authority to admit and rely on reliable hearsay. Richardson held that physician reports adduced by the agency were admissible and satisfied the requirement of "substantial evidence" though opposed by live expert testimony on behalf of claimant.

Enactment of the Federal Evidence Rules in 1975, however, brought about a perceptible change in attitude in Congress and in several of the administrative agencies themselves. McCormick, Evidence § 351. No longer was it assumed that formal evidentiary rules would not apply in any given administrative agency hearing.

Presently, four types of agency rules exist: (1) Rules following the wide open standard of the APA, see, e.g., 16 C.F.R. § 3.43(b) (FTC); 43 C.F.R. § 4.122 (Interior), (2) Rules that permit use of the FRE as a source of guidance, (3) Rules requiring that presiding officers apply the Federal Rules of Evidence "so far as practicable," and (4) Rules adopting the Federal Rules of Evidence without qualification, see 29 C.F.R. § 2200.72 (OSHA).

As of the mid-1980s, of 280 evidentiary regulations, 37 made reference to the Federal Rules of Evidence, most requiring their use "as far as practicable." McCormick, Evidence § 351; citing Pierce, Use of the Federal Rules of Evidence in Federal Agency Adjudications, 39 Admin. L. Rev. 1, 6 (1987). Only the Occupational Safety and Health Review Commission has adopted the Federal Rules of Evidence without qualification. See 29 C.F.R. § 2200.71.[11/]

Alarmed by the increasing application of the Federal Rules of Evidence in administrative hearings, the Administrative Conference of the United States on June 20, 1986, adopted Resolution 86-2(1). According to Kenneth Davis, this recommendation "now overshadows all other law about evidence in administrative proceedings," and "is about as effective as a statute

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11/ Prior to implementing the present rule, OSHRC allowed use of the Federal Rules of Evidence "insofar as practicable." In proposing the present rule, OSHRC stated that the "insofar as practicable" standard created "uncertainty," and that "it is difficult to imagine a situation in which it would not be 'practicable' to follow the Federal Rules of Evidence." 51 Fed.Reg. 23190 (June 25, 1986). OSHRC stated that "[i]n practice, the Commission expects that the revision of its rule on the admissibility of evidence would have only a limited effect on Commission proceedings...Even as to hearsay, where the Federal Rules were previously not followed strictly, the change to a strict application of the hearsay rules probably will not result in a significantly different resolution of factual issues. Often, evidence admitted under the Commission's lenient policy towards hearsay also would have been admissible under the Federal Rules."

to the same effect would be." Davis, Administrative Law of the Eighties, 1989 Supplement to Administrative Law Treatise 382. Resolution 82-6 provides:

> Congress should not require agencies to apply the Federal Rules of Evidence, with or without the qualification "so far as practicable," to limit the discretion of presiding officers to admit evidence in formal adjudications.
>
> Agencies should adopt evidentiary regulations applicable to formal adversarial adjudications that clearly confer on presiding officers discretion to exclude unreliable evidence and to use the weighted balancing test in Rule 403 of the Federal Rules of Evidence, which allows exclusion of evidence the probative value of which is substantially outweighed by other factors, including its potential undue consumption of time.
>
> To facilitate the efficient and fair management of the proceeding, when otherwise appropriate, an agency should announce in advance of a formal adjudication as many of the factual issues as the agency can foresee to be material to the resolution of the adjudication.

As we have seen, regulatory proceedings also apply statutory substantive standards that are often immeasurably more risk-adverse than the "more likely than not" causation standard of civil litigation, since the aim is prospective prevention of harm rather than retrospective assignment of responsibility for loss. See n. 5, supra. Moreover, federal regulatory statutes ordinarily (but not always; see p. 4, supra) entrust the ultimate determination to expert decisionmakers with the background to give due weight to scientific evidence that lay juries may not have.

These differences between jury trials and agency regulatory proceedings may well support the exclusion of some scientifically relevant evidence, used by federal agencies in making risk

assessment decision, under the contextual approach of Fed. R. Evid. 403, for tendency to confuse or prejudice the jury. Those differences may also permit the grant of summary judgment to defendants where an agency would conclude that the risk is unreasonable and should be abated, because of the difference in the applicable substantive standard in civil litigation. The practice and judgment regarding the difficulty of extrapolating conclusions about human risk factors from available scientific methodologies, and the need therefore to consider a broad range of evidence in drawing such conclusions, is nonetheless of paramount importance in condemning the contrary, per se exclusionary approach of the courts below.

CONCLUSION

For the reasons stated above, the judgment of the Ninth Circuit should be reversed.

Respectfully submitted,

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APPENDIX

STATEMENT OF INTEREST OF AMICI CURIAE

The American Society of Law, Medicine and Ethics was founded in 1972 to provide a forum for interdisciplinary discussion of the complex issues at the interface of law, medicine, ethics and health. Ongoing informational efforts include the publication of two quarterly journals, Law Medicine and Health Care, a leading forum for interprofessional analysis of current issues, and the American Journal of Law, Medicine and Ethics, a law review co-published with the Boston University School of Law. For the reasons stated in the attached brief, the Society believes that all valid and reliable scientific research, conducted according to professional standards, should be admissible in legal proceedings.

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Donald R. Mattison, M.D., is Dean of the Graduate School of Public Health and Professor of Environmental and Occupational Health and Obstetrics and Gynecology at the University of Pittsburgh. From 1978 to 1984, Dr. Mattison was director of the reproductive toxicology program in the Pregnancy Research Branch, National Institute of Child Health and Human Development, National Institutes of Health. From 1984 to 1990, he was Professor of Obstetrics and Gynecology and Toxicology at the University of Arkansas for Medical Sciences. During this period he also served as acting director of the human risk assessment program at the National Center for Toxicological Research, a component of the Food and Drug Administration. Dr. Mattison has published widely in the area of reproductive toxicology, and, among other activities, was editor of a volume entitled Reproductive Toxicology, published by the American Journal of Industrial Medicine (vol. 4, Number 1/2, 1983).

The National Resources Defense Council (NRDC), a nonprofit corporation whose principal place of business is at 122 East 42nd Street, New York, NY, has offices in Washington, D.C. and San Francisco, CA, and a membership of more than 175,000 persons from across the United States and in several other nations. NRDC is dedicated to the preservation, enhancement and defense of the human environment and natural resources of the United States. In carrying out these objectives, NRDC has undertaken efforts both before government regulatory bodies and the courts to obtain clean air, clean water and toxic substances control, including activities to ensure effective implementation of health and environmental protection statutes. In connection with these activities, NRDC has on numerous occasions relied upon and supported governmental reliance upon both laboratory animal and epidemiological animal studies to assess the risks that exposure to chemicals poses to humans, including studies that have and have not been formally peer-reviewed.

The Program on Gender, Science and Law at the Columbia University School of Public Health is a multidisciplinary program composed of scientists, lawyers, and scholars who are

dedicated to exploring mixed issues of science, law and public policy, particularly in areas that affect women's health and well-being. Faculty members associated with the Program have substantial expertise applying scientific knowledge to resolution of legal disputes, have made scholarly study of these issues, and have dealt with them on a practical level as attorneys and expert witnesses.

Allen Rosenfield, M.D., is Dean of the School of Public Health at Columbia University, DeLamar Professor of Public Health, and Professor of Obstetrics and Gynecology. Before assuming this position, Dr. Rosenfield had a distinguished career in family planning and maternal and child health, both nationally and internationally. Dr. Rosenfield is a diplomate of the American Board of Obstetrics and Gynecology, a fellow of the American College of Obstetrics and Gynecology, and a Member of the Institute of Medicine. He serves on numerous boards and committees, acts as advisor to governmental agencies and other organizations, and has published more than 85 scientific articles.

Ellen K. Silbergeld, Ph.D., is Professor of Epidemiology at the University of Maryland School of Medicine. Prior to this, she was Chief of the Section on Neurotoxicology, National Institute of Neurological Diseases and Stroke at the National Institutes of Health, Guest Scientist in the Reproductive Toxicology Section, Pregnancy Research Branch at NIH, and Chief Toxics Scientist and Director of the Toxics Chemical Program at the Environmental Defense Fund. She has served on the editorial boards of eight scientific journals and is a member of the Board of Scientific Counselors of the National Institute of Environmental Health Sciences at NIH. She has been a consultant on occupational and environmental health to, among others, the U.S. Secret Service, the Environmental Protection Agency, and the Food and Drug Administration, and has published more than 100 scientific articles.

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IN THE
Supreme Court of the United States
October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, INDIVIDUALLY AND AS GUARDIANS AD LITEM FOR JASON DAUBERT, AND ANITA DE YOUNG, INDIVIDUALLY AND AS GUARDIAN AD LITEM FOR ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Brief *Amici Curiae* of Physicians, Scientists, and Historians of Science in Support of Petitioners.

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BRIEF *AMICI CURIAE* OF RONALD BAYER, STEPHEN JAY GOULD, GERALD HOLTON, PETER INFANTE, PHILIP LANDRIGAN, EVERETT MENDELSOHN, ROBERT MORRIS, HERBERT NEEDLEMAN, DOROTHY NELKIN, WILLIAM NICHOLSON, KATHLEEN JOY PROPERT AND DAVID ROSNER IN SUPPORT OF PETITIONERS.

INTEREST OF *AMICI CURIAE*

Amici are physicians, practicing scientists, historians of science, and scholars of the sociology of science who express no opinion on the merits of the plaintiffs' case and who have no interest in the outcome of this lawsuit.[1] *Amici* appear in their own behalf to alert the Court to the grave misunderstanding of science on which the decision below is predicated — a misunderstanding that threatens the integrity and accuracy of every federal court proceeding which depends on opinion testimony from scientists. If federal juries are going to rely on expert scientific testimony in deciding cases, then federal judges must have a proper understanding of the nature of scientific inquiry and of how practicing scientists work. This in turn requires recognition of the fact that scientists often disagree, and that different analyses of the very same data can often yield different conclusions. The need to understand how the work of scientists may be used in courts of law even when those scientists disagree transcends the perspectives of the parties in this case — indeed, it transcends even the perspective of any particular class of litigation such as tort cases — and without their participation here, *amici* fear that this issue might not be fully ventilated before this Court.[2]

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[1] The qualifications of and positions held by *amici* are set forth in the appendix bound with this brief.

[2] Counsel for all parties have consented to the filing of this brief. Letters of consent have been filed with the Clerk.

SUMMARY OF ARGUMENT

The decision below adopts a rule of admissibility, derived from *Frye v. United States*, that is premised on a remarkable misunderstanding of the nature of scientific inquiry. The Ninth Circuit held that certain expert testimony from scientists of unchallenged qualifications was wholly inadmissible because the methods of research and analysis employed by those scientists were, supposedly, not "generally accepted" by what the court referred to, without further elaboration, as the "scientific community." Yet the Ninth Circuit did not even purport to investigate the scientific methodology in question, nor did it survey the "scientific community" to determine just what the "consensus" was. Instead, the court below examined the *conclusions* reached by plaintiffs' experts, and then blithely concluded that the methodology of these scientists' studies was "problematic" — and therefore *per se inadmissible* — simply because their analyses had not been published in a peer-reviewed journal and because they reached a conclusion that contradicted what the court deemed to be a significant body of opposing evidence.

Judgments based on scientific evidence, whether made in a laboratory or a courtroom, are undermined by a categorical refusal even to consider research or views that contradict someone's notion of the prevailing "consensus" of scientific opinion. Science progresses as much or more by the replacement of old views as by the gradual accumulation of incremental knowledge. Automatically rejecting dissenting views that challenge the conventional wisdom is a dangerous fallacy, for almost every generally accepted view was once deemed eccentric or heretical. Perpetuating the reign of a supposed scientific orthodoxy in this way, whether in a research laboratory or in a courtroom, is profoundly inimical to the search for truth. A categorical refusal even to examine and consider scientific evidence that conflicts with some ill-defined notion of majority opinion is a recipe for error in any forum.

Unable or unwilling to investigate scientific methodology and determine just what is orthodox and "generally accepted," the Ninth Circuit instead seized upon publication in a peer-reviewed scientific journal as the badge of respectability, the *sine qua non* of admissible "good science." The court thereby converted that editorial tool into something no scientist or journal editor ever meant it to be: a litmus test for scientific truth. This is not the way scientists work in their laboratories and symposia, and it is not the way that science should be used in the courtroom if the goal is to ensure the most accurate and valid judgments possible.

ARGUMENT

THE NINTH CIRCUIT'S RULE OF ADMISSIBILITY, DERIVED FROM *FRYE V. UNITED STATES*, IS PREMISED ON A FUNDAMENTAL MISUNDERSTANDING OF THE NATURE OF SCIENTIFIC INQUIRY, AND WILL FORCE TRIERS OF FACT TO MAKE DECISIONS WITHOUT ACCESS TO ALL RELEVANT EVIDENCE.

Expanding on the reasoning of *Frye v. United States*, 293 F.2d 1013 (D.C.Cir. 1923), the court below held that in order for a scientific opinion to be admissible, the methodology employed by the scientist to reach the opinion must meet "the essential requirements" imposed "by the scientific community." (A5).[3] Without reference to *any* authority drawn from the scientific community, the Ninth Circuit then served up the bald assertion that the "requirements" of that community include publication of the expert's study. (A5). It concluded that unless an expert scientific study reflects the "consensus"

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[3] Citations in this form refer to the appendices bound with the Petition for Writ of Certiorari.

of the pertinent field and has been published in a peer-reviewed journal, then it is not "good science" and is *per se* inadmissible in a federal court. (A5).

Although the courts below purported to determine the admissibility of plaintiffs' expert testimony by asking whether the methodology of the experts' studies was "a generally accepted scientific technique" (A4), it is plain from the face of their opinions that the courts were in fact interested only in deciding whether those experts' *conclusions* were generally accepted.

For example, with respect to one expert's reanalysis of previously compiled epidemiological data about Bendectin, the Court of Appeals did not even purport to investigate the soundness or professionalism of the expert's approach. Instead, it simply asserted, without reference to any authority drawn from the scientific community, that reanalysis is "generally accepted by the scientific community" only when it is subject to peer-review and published. (A4; *see also* A5).[4] In fact, reanalysis is generally accepted as a valid technique whether or not the specific reanalysis in question has been peer-reviewed and published. Indeed, the District Court noted without reservation or criticism that plaintiffs' epidemiologists and biostatisticians based their opinions "on techniques that are generally and reasonably relied upon by biometrists, epidemiologists and biostatisticians." (A13).

Nor did the courts below question the soundness, quality, or professionalism of the animal studies, *in vitro* studies, and pharmacological and toxicological research on which plaintiffs' experts relied. (A11-13) (District Court's review of evidence). Significantly, the qualifications of plaintiffs' expert

[4] The only authority cited was a single law review article. (A4).

scientific witnesses were not challenged by the defendant or by either court below.

Instead of directly evaluating the methodology of the research on which plaintiffs' experts relied, the Ninth Circuit began with those experts' conclusions and worked backwards. Thus, the Court of Appeals examined the *result* of one witness's reanalysis of epidemiological data — the same published data relied upon by the defendants' witness — and then opined that this reanalysis was "particularly problematic in light of the massive weight of the original published studies supporting the defendant's position, all of which had undergone full scrutiny from the scientific community." (A4). This "massive weight" — which obviously relates to the conclusions reached by the studies, rather than to their methodology — was thought to flow from the fact that "no published epidemiological study had demonstrated a statistically significant association between Bendectin and birth defects." (A2).

While purporting to search for a "consensus" in the *scientific* community to justify its limits on the permissible scope of expert testimony, the Court of Appeals in fact searched only for a "consensus" in the *legal* community, by looking at how other courts have treated various forms of scientific evidence in Bendectin cases. Thus, the Ninth Circuit's ruling of inadmissibility turned *not* on the methodology of the underlying research, *nor* on the caliber and nature of the experts' analytical methods, *nor* even on the nature of some supposed "consensus" in the scientific community, but on the fact that these experts' analyses had not been published (A4, A5), and on the fact that their conclusions contradicted what the Ninth Circuit took to be the conventional wisdom. (A4).

This myopic mode of decision-making — which refuses even to consider research that is deemed to be at odds with the prevailing wisdom — strikes *amici* as an unsound basis on

which to predicate government action influenced by scientific testimony. As scientists, physicians, historians of science and sociologists of science who are members of the "scientific community," *amici* can assure the Court that this is not how scientists work in their pursuit of truth. *Amici* challenge the Ninth Circuit's premise that the only "good science" is that which is "generally accepted" and published in peer-reviewed journals, and reject the notion that scientific analysis and conclusions that might diverge from what a court deems the published "consensus" are so unreliable as to be wholly unworthy of consideration. The quality of a scientific approach or opinion depends on the strength of its factual premises and on the depth and consistency of its reasoning, not on its appearance in a particular journal or on its popularity among other scientists. Even if it were possible to determine the existence and character of a "consensus," which is itself a task fraught with difficulty, prevailing views and conventional wisdom have all too often been consigned to the dust heap of the history of science. If the purpose of the Federal Rules of Evidence is to enable the fact-finder to make the most informed decision possible, by providing the assistance of qualified experts who possess "scientific, technical or other specialized knowledge [that] will assist the trier of fact to understand the evidence or to determine a fact in issue," Fed.R.Evid. 702, then it would be a grave mistake to require that all scientific analysis be supported by a consensus and published in a particular form in order to be considered.

A. Scientific Inquiry, Like the Fact-Finding Process in the Law, is Undermined By a Categorical Refusal Even to Consider Views or Analysis That Challenge the Supposed Conventional Wisdom.

The Ninth Circuit's almost cursory conclusion that the only science worth considering is that which reflects some undefined "consensus" in the field is predicated on two fallacious assumptions about the nature of scientific inquiry.[5]

First, the court below assumes that science always progresses by the continuous accumulation of objective, irrefutable truths, which are gradually incorporated into a consensus reflected in the scientific literature. This is incorrect. "[A] new theory, however special its range of application, is seldom or never just an increment to what is already known. Its assimilation requires the reconstruction of prior theory and the reevaluation of prior fact, an intrinsically revolutionary process." Thomas Kuhn, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS 7 (2d ed. 1970). Thus, "[s]cience advances primarily by replacement, not by addition." Stephen Jay Gould, THE MISMEASURE OF MAN 322 (1981). The conventional scientific wisdom is as often a stumbling-block as a stepping-stone to better understanding. The English philosopher and scientist Roger Bacon recognized seven centuries ago that among the "very significant stumbling-blocks in the way of grasping the truth, which hinder every man however learned, [are] . . . unworthy authority, longstanding custom, [and] the feeling of the ignorant crowd." OPUS MAJUS (1267).

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[5] It is unsurprising that the Ninth Circuit's narrow concept of "good science" is so misguided, since in reaching its definition the court relied not on the experience of practicing scientists and historians of science, but exclusively on the authority of a single attorney. (A5)(citing P. Huber, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTHOUSE 228 (1991)).

The later philosopher and essayist Francis Bacon agreed that "men have been kept back as by a kind of enchantment from progress in the sciences by reverence for antiquity, by the authority of men counted great in philosophy, and then by general consent." NOVUM ORGANUM, Aphorism LXXXIV (1620). This is because "[t]he human understanding is no dry light, but receives infusion from the will and affections . . . . Therefore [a person] rejects . . . things not commonly believed, out of deference . . . " *Id.*, Aphorism XLIX. Science is a cultural, "socially embedded activity." Gould, *supra*, at 21. Facts are not unsullied, pristine bits of truth, because culture influences what we see and how we see it. *Id.* And theories "are not inexorable inductions from facts," but imaginative visions superimposed on those facts, and that imagination is itself an artifact of society and culture. *Id.* at 22. *See also* T. Kuhn, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS 35-36, 52, 64, 90, 153 (2d ed. 1970).

Because scientific conventions, like all other cultural conventions, resist change, "[i]t would be far more realistic to think of the history of science as a continuous, sometimes desperate struggle . . . ." Thomas Goldstein, THE DAWN OF MODERN SCIENCE 245 (1980). In the words of the Spanish philosopher Jose Ortega y Gasset, "[t]he man who discovers a new scientific truth has previously had to smash to atoms almost everything he had learnt, and arrives at the new truth with hands bloodstained from the slaughter of a thousand platitudes." THE REVOLT OF THE MASSES Ch.XIV (1930).

The Ninth Circuit's second fallacy is the assumption that scientific truths, once discovered, are complete, universal, immutable and eternal. The defendants have urged this Court that the expert testimony excluded here was inadmissible because it supposedly challenged "universally recognized scientific truths." Brief in Opposition at 2. Without passing judgment on the assertion that the safety of Bendectin rises to the level of a "universally recognized scientific truth," *amici*

would remind the Court of Alfred North Whitehead's dictum that "[t]here are no whole truths; all truths are half-truths. It is trying to treat them as whole truths that plays the devil." DIALOGUES 16 (1916).[6]

With respect to epidemiology in particular, the eminent biostatistician, Sir Austin Bradford Hill, has cautioned that "we can[not] usefully lay down some hard-and-fast rules of evidence that must be obeyed before we can accept cause and effect," because "[a]ll scientific work is incomplete — whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer on us a freedom to ignore the knowledge we already have, or to postpone action that it appears to demand at a given time." Hill, *The Environment and Disease: Association or Causation?*, 58 PROCEEDINGS OF THE ROYAL SOCIETY OF MEDICINE 295, 299-300 (1965). As the editor of the JOURNAL OF THE AMERICAN PUBLIC HEALTH ASSOCIATION has pointed out, "conclusiveness in inferring causality — in epidemiology as with all studies of free-living human beings — is a desire more often than an accomplishment." Susser, *Rules of Inference in Epidemiology*, 6 REGULATORY TOXICOLOGY AND PHARMACOLOGY 116, 127 (1986). As a consequence, those who seek in science the immutable truth they find lacking in the law are apt to be disappointed:

> One notable similarity [between law and epidemiology] is the dependence of both fields upon subjective judgments.
>
> * * *

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[6] *See also* I RESPONSIBLE SCIENCE: ENSURING THE INTEGRITY OF THE RESEARCH PROCESS 38 (Nat'l Academy of Sciences) (1992) ("Although its goal is to approach true explanations as closely as possible, [science's] investigators claim no final or permanent explanatory truths. Science changes. It evolves."),

> In the end, a quality which lawyers should understand better than any — judiciousness — matters more than any. Scientists use both deductive and inductive inference to sustain the momentum of a continuing process of research. . . . The courts of law, and the courts of application, use inference to reach decisions about what action to take. Those decisions often cannot rest on certitudes, most especially when population risks are converted into individual risks.

Id. at 116, 128. *See generally,* M. Susser, CAUSAL THINKING IN THE HEALTH SCIENCES: CONCEPTS AND STRATEGIES IN EPIDEMIOLOGY (1973).

These reservations about scientific truth and certainty plainly went unheeded in the court below. Consider, for example, the Ninth Circuit's cursory dismissal of the technique of reanalysis of epidemiological data. (*See* A5). To take the data compiled or used in a previous study and to subject it to fresh calculation and statistical analysis is an unremarkable step, akin to auditing a previously completed financial report or to submitting medical records and complex test results to another physician to obtain a second opinion.[7] Indeed, the District Court itself characterized the reanalysis performed in this case as "'the methodology that is generally and reasonably relied upon by epidemiologists to analyze, study and interpret data that has been collected.'" (A12).[8]

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[7] *See also* Gould, THE MISMEASURE OF MAN, *supra* (discussing history of numerous reanalyses of IQ data compiled by early intelligence researchers, which uncovered many fatal errors, some egregious and some subtle).

[8] The District Court's objection to these studies seems to have been based not on their methodology, but solely on the fact that they were not published in a peer-reviewed journal. (A14-15). *See also* A4-5 (same position taken by Ninth Circuit). This issue is dealt with below in Part B.

Without delving into the possible virtues or limitations of this particular epidemiological tool, we point out that much if not most advancement in science comes from looking at the same old facts in a different way. Science "lies not in discovering facts, but in discovering new ways of thinking about them." A.Bragg, *The Atom,* in THE HISTORY OF SCIENCE 167 (1948). "In a growing research discipline, inquiry is directed . . . to the discovery of new patterns of explanation." N. Hanson, PATTERNS OF DISCOVERY 2 (1958). "The paradigm observer is . . . the man who sees in familiar objects what no one else has seen before." *Id.* at 30. *See also* Kuhn, *supra*, at 111.

In defending the decision below, the respondents cling nevertheless to a strangely idealized notion of scientific inquiry, arguing that the testimony of plaintiffs' experts must be ruled inadmissible because it contradicts a huge body of evidence and is therefore nothing less than "*heresy.*" Brief in Opposition at 1, 3 (emphasis added). The use of such a term, in this century, to characterize testimony by reputable scientists of unchallenged qualifications, is truly astonishing. This approach, which was embraced by the Ninth Circuit, would enshrine a court's notion of consensus or majority opinion as scientific orthodoxy and silence all dissenting voices. The rule of orthodoxy may have a place in theology, but there is no place for dogma in science.[9]

To begin with, there is the vexing problem of deciding precisely what the orthodox position is. Scientific disciplines have neither pontiffs to determine official positions nor papal encyclicals to promulgate them. The Ninth Circuit relies on notions of "general acceptance" and "consensus" (A5), but

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[9] Joseph Priestly, the 18th century chemist who discovered oxygen, reflected on the dangers of conventional wisdom in his MEMOIRS, and quoted William Warburton, the Bishop of Gloucester: "Orthodoxy is *my* doxy; heterodoxy is another man's doxy." Vol. I at 572.

these unelaborated formulations beg more questions that they answer.[10]

For example, here the Ninth Circuit defined the "consensus" of the "scientific community" — on the issue of what evidence is pertinent to evaluating Bendectin's role in birth defects — entirely in terms of "published epidemiological stud[ies]" (A2), without regard to a wealth of evidence drawn from the fields of teratology, pharmacology, toxicology, pathology and clinical medicine. (A3; *see also* A13-14). The court held that no jury should even be allowed to consider this other larger, more diversified body of evidence. Yet epidemiologists themselves recognize that the "epidemiologist needs the contributions of many other disciplines in order to pursue his own." B. MacMahon & T. Pugh, EPIDEMIOLOGY: PRINCIPLES AND METHODS 15 (1970).[11] This is why federal public health authorities, including the Environmental Protection Agency and the Occupational Safety and Health Administration, make a policy of considering and relying on human, animal and laboratory studies in addition to statistical epidemiological evidence, which those agencies deem incomplete.[12]

[10] The Ninth Circuit's embrace of publication in peer-reviewed journals as the badge of orthodoxy will be discussed below in Part B.

[11] "While epidemiologic information is at times derived from a much wider spectrum of biologic and medical disciplines, these three — clinical medicine, pathology and biostatistics — have almost universal application in epidemiology. Indeed, epidemiology may be thought of as the joint application of the three in search for further understanding of disease etiology." MacMahon and Pugh, *supra*, at 16. *See also* Silbergeld, *The Role of Toxicology in Causation: A Scientific Perspective*, 1 COURTS, HEALTH SCIENCE AND THE LAW 374 (1991).

[12] *See, e.g.*, Environmental Protection Agency, Final Guidelines for Developmental Toxicity Risk Assessment, 56 FED. REG. 63798, 63799 (1991) ("Hazard identification/dose-response evaluation involves *examining all available experimental animal and human data* . . . to determine if an agent causes developmental toxicity") (emphasis added); EPA, Proposed Guidelines for Assessing Female Reproductive Risk, 53 FED. REG. 24834, 24836 (1988)(EPA consistently relies on "evaluation of *toxicological data from humans and experimental animals*" in assessing reproductive and developmental risks) (emphasis added); Occupational Safety and Health Administration, Final Standard for Occupational Exposure to Ethylene Oxide, 49 FED. REG. 25734, 25743 (1984) (OSHA ruling rested on a "*comprehensive* review of the scientific evidence . . . based on information from *many investigations in several species of experimental animals* . . . as well as positive results from several *human studies*") (emphasis added); OSHA, Final Rule for Identification, Classification and Regulation of Potential Occupational Carcinogens, 45 FED. REG. 5002, 5040-59 (1980) ("non-positive" epidemiological data "will rarely provide evidence to offset scientifically evaluated positive results . . . observed either from *other human studies or from experimental studies in test animals*") (emphasis added).

Epidemiology at best establishes a statistical probability that a particular chemical agent causes a particular effect, but the absence of such a statistical relationship does not prove the absence of a causal link.[13] Statistics alone cannot prove causality, but can at most establish correlations, which are merely suggestive of causation. Other disciplines focus on the causal mechanism itself by examining the chemical and biological processes that may lead to an injury. It strikes *amici* as more than passing strange, for example, for the courts below to have excluded testimony based on teratological research — which deals with the development of biological malformations — when the issue is whether a drug causes birth defects. One's concept of "general acceptance" or majority opinion in the "scientific community" thus turns on the way in which one defines the "community" at the outset.

Some courts have rejected the *Frye* approach precisely "because the general acceptance test was too vague and malleable to yield consistent results, and because its nose-counting emphasis often led to the exclusion of helpful evidence in contradiction to the spirit of the Federal Rules of

[13] "A high-quality negative epidemiological study, while useful, cannot prove the absence of an association. . . ." Office of Science and Technology Policy, Chemical Carcinogens: A Review of the Science and its Associated Principles, 50 FED. REG. 10372, 10378 (1985).

Evidence." *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 955 (3d Cir. 1990).[14] Which noses would one count? If the scientist whose testimony is in question is a qualified expert, why wouldn't her voice count and suffice to destroy "consensus"? How many supposed "dissenters" does it take to negate consensus? This quandary may suggest why Congress enacted Fed.R.Evid. 702, whose requirements for "Testimony by Experts" mention no role for the federal judiciary in determining scientific consensus or checking for peer-reviewed publication as prerequisites to admissibility.

More importantly, the exclusion of scientific testimony that the respondent deems "heresy" is inimical to the search for truth. Advancement in scientific understanding frequently comes from what was once denounced by many as unorthodox. Indeed, as Thomas Huxley once remarked, "[e]xtinguished theologians lie about the cradle of every science as the strangled snakes beside that of Hercules." DARWINIANA. THE ORIGIN OF SPECIES (1860). Columbus was scorned as a renegade geographer. *See* Samuel Eliot Morison, ADMIRAL OF THE OCEAN SEAS (1940). Galileo was persecuted by the Inquisition for challenging the geocentric orthodoxy promoted by the Aristotelian scientists who dominated the academies and universities. *See* H. Kearny, SCIENCE AND CHANGE: 1500-1700 146-49 (1971).[15]

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[14] *See also State v. Williams*, 446 N.E.2d 444, 448 (Ohio 1983) (rejecting *Frye* because there is no wisdom "in scientific nose-counting for the purpose of deciding whether evidence based in newly ascertained or applied scientific principles is admissible.").

[15] The rule of scientific orthodoxy that the Ninth Circuit and respondent would engraft onto the Federal Rules of Evidence is no longer in vogue even in theological circles: the Vatican formally rehabilitated Galileo and renounced its four centuries of condemnation of his ideas on October 31, 1992. *See* N.Y. Times, Oct. 31, 1992, at A1, col. 1.

The phenomenon of yesterday's heresy becoming tomorrow's conventional wisdom is as current as the morning newspaper. For example, on November 17, 1992, the *New York Times* reported the discovery that plants, even though they lack nerve tissue, use electrical signals to alert their defense systems against threats such as grazing caterpillars. N.Y. Times, Nov. 17, 1992, at C1, col. 2 (discussing revelations in the Nov. 5, 1992 issue of NATURE). This discovery "jolted" the scientific community because "the study of electrical signaling [in plants] ha[d] long been shunned" by "most serious scientists." *Id.* "Things got so bad that even by suggesting that an electrical message could be an important signal in plant cell communication a scientist could open himself to ridicule. 'Plant electrophysiology was squelched,' said Dr. Pickard. 'It was reduced to the level of spoon bending.'" *Id.* at C13, col.1.[16]

These examples and a thousand more underscore the wisdom of Bertrand Russell's "Seventh Commandment": "Do not fear to be eccentric in opinion, for every opinion now accepted was once eccentric." But the decision below is in fact even more dangerous than this suggests, for there was nothing "eccentric" about the reanalysis of epidemiological data or about the toxicological and pharmacological methodologies relied upon by the scientists whose testimony was excluded here. Neither court below purported to find anything unsound or unprofessional in the work of plaintiffs' experts: these research techniques were deemed "problematic" because of the supposed "massive weight of the original published studies supporting the defendant's position." (A4).

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[16] Mainstream plant researchers had become "enamored instead with chemical messengers, or hormones," and spent decades seeking in vain to isolate hormonal messengers that they had postulated and even named, while ridiculing the possibility of electrical communication. N.Y. Times, Nov. 17, 1992, at C13 col. 1. "'People have been trying to force a hormones explanation on everything,'" said Dr. Eric Davies, professor of biology at the University of Nebraska. *Id.* at C13, col. 3.

Testimony based on such research may, of course, ultimately be rejected in favor of conflicting evidence. But in scientific inquiry, such a rejection should be a deliberative determination that the rejected view is incorrect, *not* a threshold assumption that the view is *per se* unworthy of consideration simply because it does not concur with someone's idea of the majority position.

Indeed, we would think that the approach taken by the Ninth Circuit and promoted by the respondent is inimical to the search for truth in *any* discipline, not just in science. When a court is confronted by a body of legal scholarship, does it automatically refuse to consider the arguments and views of scholars whose position disagrees with the majority view in academe, or whose arguments are presented in an *amicus* brief rather than in a previously published law review article? When this Court must resolve a question of law on which the Courts of Appeals are divided 10 to 2, does it automatically dismiss the holdings of the courts in the minority without weighing their analysis? If a jury is asked to decide a question of fact on which qualified scientific testimony would be of assistance, we believe that the search for truth would be aided by allowing the jury to consider — as a practicing scientist would — *all* of the relevant evidence, not just that which a particular judge deems to reflect the consensus of scientific opinion.

B. The Ninth Circuit's Elevation of Publication in Peer-Reviewed Journals To The *Sine Qua Non* of Admissible "Good Science" Is Insupportable.

The Ninth Circuit's test for whether scientific research meets its admissibility standards of "general acceptance" and "consensus" ultimately boils down to a requirement that the study or research on which a scientist would base her opinion

have been published in a peer-reviewed journal. (A4-5). But the appearance of a study in a peer-reviewed journal does not necessarily mean that the study is generally accepted or even sound. Conversely, the fact that a study has not been published in a peer-reviewed journal does not mean that the study and any opinion based thereon are unreliable and would be of no help in resolving a question of fact.

The peer review process that precedes publication in many scientific journals is valuable, to be sure, but the Ninth Circuit is confused about the purpose and limits of that process. Peer review is a vital editorial tool whose "main functions," in the words of Dr. Arnold S. Relman, then editor-in-chief of the New England Journal of Medicine, are "to improve the quality of what is published" and "to help editors decide what they want to publish in their journals." L.A. Times, May 22, 1989, Pt. II, at 3 col. 1. The Ninth Circuit has made a fetish of publication, even though peer review takes place in many fora within the scientific community other than journals: peer review of papers submitted for presentation at conferences and meetings; review of grant applications; review by advisory committees. But "the peer review process is 'not meant to determine ultimate truth or falsity.'" *Ibid.* (quoting Dr. Relman, *supra*). As a former editor of the Journal of the American Medical Association has remarked, "[p]eer review is far from being a 'perfect sausage machine for grinding out the truth.' . . . 'Just because peer review is about a review of scientific data doesn't mean that it is itself a scientific process.'" *Id.* (quoting Elizabeth Knoll).[17]

Whether a particular scientist's research has been published in a peer-reviewed journal may be relevant to how much

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[17] *See generally* D. Chubin & E. Hackett, Peerless Science: Peer Review and U.S. Science Policy (1990) (discussing inherent limitations in peer review process); S. Harnad, ed., Peer Commentary on Peer Review: A Case Study in Scientific Quality Control (1982) (same).

weight the study is accorded by other scientists or by a government decision-maker, be it a civil jury or a regulatory agency. But the Ninth Circuit has made peer review into something it never claimed to be: a talisman of truth. It is unsurprising that the court below cites no scientific authority whatsoever for the outlandish proposition that unpublished studies are *per se* unreliable and unworthy of any consideration.[18] For medical experts routinely rely on the unpublished (and sometimes even unwritten) observations and opinions of other experts in diagnosing, treating, and determining the cause of disease, just as research scientists rely on the as-yet unpublished work of their colleagues.

Moreover, federal regulations expressly authorize federal regulatory agencies to rely on unpublished scientific research in determining health hazards and in crafting safety standards to protect the public. Regulations promulgated under the Toxic Substances Control Act require manufacturers to submit to the Environmental Protection Agency lists of *unpublished* health and safety studies regarding toxic substances contained in their products, in order to assist the agency in assessing the health risks posed by the products. 40 C.F.R. §716.35(3), (4). The Department of Agriculture requires that petitioners seeking reclassification of a genetically-altered plant as a non-pest submit "copies of *unpublished* studies, or data from tests performed." 7 C.F.R. §340.4(b) (emphasis added). These regulations reflect an understanding that the adoption of federal standards protecting the public health "cannot be postponed because definitive medical or scientific evidence is not currently available." 43 FED.REG. No. 53 11514 (Mar. 17, 1978). Such pressing and important decisions must be based on "the best available evidence" including, if necessary, unpublished data and studies. *Id.*

[18] The only authority cited by the court below was a single, ten-year-old law review article. (*See* A4).

The Ninth Circuit has set a daunting task for federal judges by mandating that they apply a vague "general acceptance" standard to screen the testimony of all qualified scientific experts before admitting their testimony to a jury.[19] It therefore comes as no surprise that the court below seized upon what it apparently took to be a quick and easy "Good Housekeeping Seal of Approval" for the scientific community — publication in a peer-reviewed journal. "Our society often wants to see peer review as a mechanical certification of truth for which no one has to take responsibility. No such mechanism is conceivable." J. Schlefer, *Truth, Beauty, and Peer Review*, TECHNOLOGY REVIEW, Oct. 1990, at 5.

[19] A different government attempt to apply a general acceptance standard to the scientific community illustrates the dangers and difficulty of automatically screening out scientific practices that supposedly depart from the norm. The Office of Scientific Integrity of the National Institutes of Health promulgated rules that defined scientific "misconduct" to include all "'practices that deviate from those that are commonly accepted within the scientific community.'" Wash. Post, March 20, 1992, at A24, col. 1 (quoting the OSI rule). The breadth and vagueness of this standard quickly provoked plans for amendment and revision. "As Dr. [Bernadine] Healy [director of the National Institutes of Health] has pointed out, this [community standard] would have implicated even the discoverer of penicillin, who serendipitously found good uses for bacteria growing in a contaminated lab dish." *Id.*

CONCLUSION

Although the "general acceptance" limitation on the admission of scientific evidence may have been intended to promote the ascertainment of truth and the achievement of justice in federal trials, *amici* believe that its application would have precisely the opposite effect. A jury, like a scientist, cannot reach the most accurate possible judgment on a scientific question if it is denied access to the relevant analysis of qualified scientists, simply because their studies have not yet been published or do not reflect some court's notion of what is generally accepted in the particular "scientific community" defined by that court. Decision-makers forced to wear such arbitrary blinders will stumble and take many unnecessary and avoidable falls. The Ninth Circuit's rule is predicated on a gross misunderstanding of scientific inquiry, and *Amici* therefore urge this Court to reverse the judgment below.

Respectfully submitted,

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APPENDIX

IDENTIFICATION OF AMICI CURIAE

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STEPHEN JAY GOULD is Alexander Agassiz Professor of Zoology, Professor of Geology, and Professor of the History of Science at Harvard University. He is also Curator of Invertebrate Paleontology in the Museum of Comparative Zoology. He is a Fellow of the American Association for the Advancement of Science, the American Academy of Arts and Sciences, and the National Academy of Sciences. He is on the editorial board of SCIENCE and has served on the editorial boards of several other journals. He is the recipient of several dozen academic medals, awards and prizes, including one of the first MacArthur Foundation Prize Fellowships. His numerous books on science and the history of science have garnered many awards, including the National Book Award and the National Book Critics Circle Award.

GERALD HOLTON is Mallinckrodt Professor of Physics and Professor of the History of Science at Harvard University. He has been Secretary of the American Academy of Arts and Sciences and was the Founding Editor of the Academy's journal, DAEDALUS. He has served on the Board of Directors of the American Association for the Advancement of Science, as President of the History of Science Society, and as Chairman of the U.S. National Commission on the History and Philosophy of Science. His numerous books include THE ADVANCEMENT OF SCIENCE, AND ITS BURDENS (1986), LIMITS OF SCIENTIFIC INQUIRY (1979), and SCIENCE AND CULTURE (1965).

PETER F. INFANTE holds a doctorate in epidemiology and a Doctor of Dental Surgery. He has worked as an epidemiologist for the Centers for Disease Control, conducting epidemiologic investigations to determine associations between exposure to toxic substances and cancer, pregnancy outcome, and other chronic disabling conditions. He has held key positions involving the review of health standards based on risk assessments and epidemiologic, toxicologic, and industrial hygiene data for the last nine years. Prior to that, Dr. Infante had major responsibility for the classification of carcinogenic substances and the establishment of the priority for their regulation. He is a Fellow of the American College of Epidemiology, and a member of other organizations related to occupational and environmental health. His current research interests are in occupationally related disease. He has over 80 publications in peer-reviewed journals.

PHILIP LANDRIGAN is the Ethel H. Wise Professor of Community Medicine at Mount Sinai School of Medicine in New York, where he is Chair of the Department of Community Medicine and Director of the Division of Environmental and Occupational Medicine. He is Editor-in-Chief of the AMERICAN JOURNAL OF INDUSTRIAL MEDICINE and ENVIRONMENTAL RESEARCH. He is Consulting Editor of ARCHIVES OF

ENVIRONMENTAL HEALTH and on the Editorial Board of the AMERICAN JOURNAL OF PUBLIC HEALTH. He has been honored by the Institute of Medicine, National Academy of Sciences and received the Meritorious Service Medal from the U.S Public Health Service.

EVERETT MENDELSOHN is Professor of the History of Science at Harvard University. He has been Vice President of the American Association for the Advancement of Science and has been on the editorial board of SCIENCE, its official journal. He has served on the Council of the History of Science Society and been President of the International Council for Science Policy Studies. He is a member of the American Association for the History of Medicine and an Editor of the JOURNAL OF THE HISTORY OF BIOLOGY. He has served on the National Academy of Sciences Committee on Life Sciences and Social Policy. His more than 60 published works include the books HUMAN ASPECTS OF BIOMEDICAL INNOVATION (1971) and THE SOCIAL PRODUCTION OF SCIENTIFIC KNOWLEDGE (1977).

ROBERT MORRIS is a physician who also holds a Ph.D. in Environmental Engineering and an M.S. in Biostatistics. He is an Assistant Professor in the Division of Epidemiology and Biostatistics at the Medical College of Wisconsin, Milwaukee. He has served, among other advisory and academic positions, as visiting scientist to the Harvard University School of Public Health and expert adviser to the National Research Council Committee on Environmental Epidemiology.

HERBERT NEEDLEMAN is Professor of Child Psychiatry and Pediatrics at the University of Pittsburgh School of Medicine. His pioneering research on the health effects of environmental lead on children became the basis for numerous public health policies, including the decision to eliminate lead from gasoline. His lead studies have become the model for

similar environmental health studies around the world. For his research, he has been honored with the First Scientific Studies Award of the Association for Children with Learning Disabilities, The Sarah Poiley Medal of the New Academy of Sciences, the Charles Dana Award for Pioneering Achievement in Public Health, and has been elected to the Institute of Medicine of the National Academy of Sciences.

DOROTHY NELKIN is a University Professor at New York University, where she teaches in the Department of Sociology and the School of Law. Her scholarship focuses on the public policies concerning science and medicine. She has served on the Board of Directors of the American Association for the Advancement of Science, on the National Academy of Sciences (NAS) Study Committee on Decision-Making in Applying Advances in Biology and Technology to Health, and on the Biotechnology Advisory Panel of the Congressional Office of Technology Assessment. She is the author or co-author of more than 170 published works, including the books SCIENCE AS INTELLECTUAL PROPERTY: WHO CONTROLS SCIENTIFIC RESEARCH? (1984), DANGEROUS DIAGNOSTICS: THE SOCIAL POWER OF BIOLOGICAL INFORMATION (1989), and CONTROVERSY: THE POLITICS OF TECHNICAL DECISIONS (3d rev.ed. 1991).

WILLIAM NICHOLSON is a Professor at the Mount Sinai School of Medicine of the City University of New York. His work at Mount Sinai has included direction of industrial hygiene studies, the development and use of analytical techniques for measurement of pollutants in various samples, the conduct of epidemiological studies on occupational cohorts, and the use of statistical analyses to establish, when possible, the dosage and time dependence of disease. Dr. Nicholson is an Advisory Editor of ENVIRONMENTAL RESEARCH, Assistant Editor of AMERICAN JOURNAL OF INDUSTRIAL MEDICINE, and he is on the Editorial Board of TOXICOLOGY AND INDUSTRIAL HEALTH.

KATHLEEN JOY PROPERT has degrees in biology and a doctorate in biostatistics. She is Assistant Professor of Biostatistics at the Harvard School of Public Health. She has published more than 40 articles in peer-reviewed journals. Much of her work has focused on design and evaluation of clinical trials of cancer therapies and treatments for pediatric HIV infection. She has performed peer reviews for CANCER TREATMENT REPORTS, BIOMETRICS, and the JOURNAL OF THE AMERICAN STATISTICAL ASSOCIATION.

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IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and As Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and As Guardian Ad Litem for ERIC SCHULLER,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF *AMICI CURIAE* OF PROFESSORS KENNETH ROTHMAN, NOEL WEISS, JAMES ROBINS, RAYMOND NEUTRA AND STEVEN STELLMAN, IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*

Amici are teachers and scholars of epidemiology. Dr. Rothman, the Editor of the journal *Epidemiology*, and a member of the Editorial Board of the *New England Journal of Medicine*, currently serves as Professor of Public Health (Epidemiology and Biostatistics) at the Boston University School of Medicine and Public Health, Adjunct Professor of Epidemiology at the Harvard School of Public Health, and Senior Epidemiologist at Epidemiology Resources Incorporated. Dr. Weiss, the author of 185 publications in the field of epidemiology, is Professor and Chairman of the Department of Epidemiology, School of Public Health and Community Medicine, at the University of Washington. Dr. Robins, Associate Editor of the *American Journal of Epidemiology*, is a Professor of Epidemiology and Biostatistics at the Harvard School of Public Health. Dr. Neutra, a past president of the International Society for Environmental Epidemiology, currently serves as Lecturer in Epidemiology at the University of California School of Public Health, Chief of the Exposure Assessment Section of the California Department of Health Services, and Acting Chief of the Environmental Health Investigations Branch of the California Department of Health Services.[1] Dr. Stellman, the author of over 60 papers in epidemiology and health sciences, currently serves as Senior Research Scientist at the American Health Foundation (where he is chief epidemiologist for studies of tobacco-related cancers), an NIH Fogarty International Fellow at the International Agency for Research on Cancer in Lyon, France, and Adjunct Associate Professor of Community Medicine at the Mount Sinai School of Medicine. More complete biographies of the *amici* appear in the Appendix to this brief.

As part of our professional duties we routinely apply the principles of epidemiology to address a wide variety of public health issues in conjunction with, and not isolated from, other traditional areas of science. *Amici* appear on their own behalf to address matters that intimately affect and threaten to alter the role

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[1] Dr. Neutra is appearing as *amicus* in his own behalf and not as a representative of any governmental agency.

of epidemiological concepts in science -- an interest that transcends the perspectives of the parties in this case and that might not otherwise be brought to the Court's attention.[2]

SUMMARY OF ARGUMENT

We have each read the decisions of the trial court and appellate court in this case. We are practicing scientists, not lawyers. We cannot and do not opine as to legal issues such as whether federal judges have the authority to supplement enacted rules for excluding evidence. Rather, we write to explain how the lower courts have misconstrued the role of epidemiology, and its limits and scope, in modern science.

Science fulfills many functions in our society. As practitioners of a discipline that seeks, but never finds, absolute truth, scientists use a variety of criteria to evaluate data in conditions that provide less than total certainty. The purpose of this brief is to demonstrate to the Court that the lower court opinions reflect a misunderstanding of scientific decision making within the context of epidemiology.

In conveying to the Court the position of *amici*, no position is taken as to whether Bendectin can be said to be a legal cause of birth defects in children. Rather, the function of this brief is to illuminate epidemiologic practices and principles that were poorly understood by the lower courts in this case. The lower courts' blind deference to inappropriate and arcane publication standards and "significance testing," reflecting methodologies held to be unacceptable by *amici* as well as many other practicing epidemiologists, will prevent valuable information from reaching legal factfinders in at least three ways. First, the standard imposed by the trial court totally misconstrues the validity and appropriateness of significance testing as a decision making tool, apparently deeming it the sole test of epidemiological

[2] Counsel to the parties have consented to the filing of this brief. Letters of consent have been filed with the Clerk.

hypotheses. Significance testing, however, is neither necessary nor appropriate as a requirement for drawing inferences from epidemiologic data. Second, by focusing on inappropriate criteria applied to determine what conclusions, if any, can be reached from any one study, the trial court forecloses testimony about inferences that can be drawn from the combination of results reported by many such studies, even when those studies, standing alone, might not justify such inferences. Third, by suggesting that an expert's "reanalysis" of published data is suspect unless itself published, the appellate court fundamentally misconstrues how epidemiologists in the real world of science function on a daily basis. Thus, the lower courts' standards prevent factfinders from learning about inferences that can be drawn from published data using generally accepted techniques.

ARGUMENT

I. THE LOWER COURTS' FOCUS ON SIGNIFICANCE TESTING IS BASED ON THE INACCURATE ASSUMPTION THAT "STATISTICAL SIGNIFICANCE" IS REQUIRED IN ORDER TO DRAW INFERENCES FROM EPIDEMIOLOGICAL INFORMATION.

The notion that only when data demonstrate "statistical significance" do epidemiologists draw inferences about observed associations between suspected risk factors and medical conditions is mistaken. Significance testing is nothing more than a statistical technique that attempts to evaluate what is called "chance" as a possible explanation for a set of observations, and classify the observations "significant" or "not significant" based on the likelihood of observing them if there were no relationship between the suspected cause and effect. Testing for significance, however, is often mistaken for a *sine qua non* of scientific inference.

It is crucial that this Court understand the distinction between these two separate and distinct processes. Scientific inference is the practice of evaluating theories. As such, it is a

thoughtful process, requiring thoughtful evaluations of possible explanations for what is being observed. Significance testing, on the other hand, is merely a statistical tool that is frequently, but inappropriately, utilized in the process of developing inferences.

Until recently, most epidemiologists were physicians. Their interest in epidemiology was focused on the occurrence patterns of a given disease. In doing so, these physicians have collaborated with statisticians who contributed expertise in making observations on large populations as well as in data analysis. As a result, much of the theoretical development of modern epidemiology has been contributed by statisticians -- Cornfield, Mantel, Cox, Breslow and Prentice -- to name but a few of the outstanding contributors. It was natural for statisticians to rely on methods of statistical analysis with which they were familiar in other areas of application. These methods have become incorporated into epidemiologic practices. Of these methods, significance testing has come to dominate and influence epidemiological practices to such an inordinate extent that undue reliance is often placed on its role in epidemiologic data analysis. Significance testing serves, however, merely as a tool for epidemiologists to achieve their scientific objectives. Indeed, the term "statistical significance" could be expunged from the lexicon of the epidemiologist with no loss; accordingly it should not be allowed to assume an importance or role in law beyond its use as an epidemiological tool. When used to evaluate the association between exposure and disease, the concept of statistical significance is often misleading and never descriptive of the magnitude of effect or the precision of measurement. Nonetheless, a factfinder who is told that a body of data is not "statistically significant" is made to believe that the data has no value. Unfortunately, the seemingly talismanic phrase "statistically significant" creates a misleading aura of infallibility totally out of relation to its actual value.

It should be noted that the motivation for the development of statistical hypothesis testing was to provide a basis for decision making in agriculture and quality-control experiments. These experiments were designed to answer questions that called for

specific actions; accordingly, the results had to be classified, if possible, into qualitatively discrete categories. Thus arose the practice of declaring associations in data as "statistically significant" or "nonsignificant" using arbitrary criteria that became conventions. Undue reliance on statistical significance (instead of more general tools of scientific inference) has resulted in, for example, the overlooking of effective new treatments because their effects were judged to be "not significant' despite the presence of an indication of efficacy in the data. Thus, testing for statistical significance, a methodologic tool, has become for some a clumsy substitute for thought, subverting what should be a contemplative thoughtful exercise into an algorithm prone to error.

It is noteworthy that the role of significance testing has been questioned by many over a long period of time. In 1970, Morrison and Henkel published a book entitled "The Significance Test Controversy" (Aldine Publishing Company, Chicago) which challenged the emerging orthodoxy of mandating that statistical significance be a central bastion of any scientific pronouncement. Several years earlier, significance testing was derided as an American obsession:

> No formal tests of significance can answer those questions. ("Is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect?") Such tests can, and should, remind us of the effects that the play of chance can create, and they will instruct us in the likely magnitude of those effects. Beyond that they contribute nothing to the 'proof' of our hypothesis." ******* "I wonder whether the pendulum, has not swung too far -- not only with the attentive pupils, but with the statisticians themselves . . . Fortunately I believe we have not yet gone so far as our friends in the USA where, I am told, some editors of journals will return an article because tests of significance have not been applied. . .

Austin Bradford Hill, *The Environment and Disease - Association or Causation?*, Proceedings of the Royal Society of Medicine (1965) 58:296-300, at 299.

Significance testing, in the view of *amici* and many other respected scientists, places too high a value on a "yes-no" answer to an oversimplified question: Is the probability that the observed association could appear by chance, even if there is no actual relationship, low enough to justify rejection of chance as the explanation of the observed association? The result of using significance testing as the criterion for decision making is that the focus is changed from the information presented by the observations themselves to conjecture about the role chance *could* have played in bringing about those observations.

One *amicus* has observed:

> With the focus on statistical significance, if chance seems to be a plausible explanation, then other theories are too readily discarded, regardless of how tenable they may be. As a result, effective new treatments have often been overlooked because their effects were judged to be "not significant," despite an indication of efficacy in the data. Conversely, if "significance" seekers find that the results of a study are calculated as improbable on the basis of chance, then chance is often rejected as an explanation when alternative explanations are even less tenable.

K. Rothman, *Significance Questing*, 105 Annals of Internal Medicine 445, 445-46 (1986) (citations omitted).

It is important to note that while, in this case, the lower courts' deference to significance testing resulted in the improper rejection of valuable information, that same undue deference could lead, in a different case, to accepting unwarranted hypotheses. For example, would any reasonable scientist accept the proposition that wearing a dress is causally related to the occurrence of breast cancer simply because the association

between the two is statistically significant? Of course not, but such is the possible misapplication of significance testing that flows from the pervasive and fundamental misunderstanding of its use.

A better approach to evaluating the error in scientific measurement is the use of "confidence intervals." A confidence interval is a range of possible values for a parameter that is consistent with the observed data within specified limits.[3] The process of calculating a confidence interval within the chosen limits is know as "interval estimation." See K. Rothman at 119.

An important advantage of interval estimation is that it:

> do[es] not require irrelevant null hypothesis to be set up nor [does it] force a decision about "significance" to be made -- the estimates can be presented and evaluated by statistical *and other* criteria, by the researcher or the reader. In addition the estimates of one investigation can be compared with others. While it is often the case that different measurements or methods of investigation or theoretical approaches lead to "different" results, this is not a disadvantage; these differences reflect important theoretical differences about the meaning of the research and the conclusions to be drawn from it. And it is precisely those differences which are obscured by simply reporting the significance level of the results.

L. Atkins and D. Jarrett, The Significance of "Significance Tests," in J. Irvine and I. Miles (eds.) *Demystifying Social Statistics* (1979). Indeed, the Court of Appeals for the Third Circuit has recognized that confidence intervals could prove to be a more acceptable basis for legal decision making than

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[3] For an analysis of confidence intervals in the legal context, see N. Cohen, *Confidence in Probability: Burdens of Persuasion in a World of Imperfect Knowledge*, 60 N.Y.U.L.Rev. 385 (1985).

significance testing. *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 945-949, 953-957 (3d Cir. 1990).

It is necessary for this Court to be aware that there is a large community of respected epidemiologists that rejects the single-minded focus on significance testing that is expressly mandated by the trial court and implicitly adopted by the appellate court, without the benefit of expert testimony or analysis memorialized in its opinion. As an example, *Epidemiology* (an epidemiology journal of which *amicus* Dr. Rothman is editor) discourages publication of articles that rely on significance testing. Recognizing this divergence of opinion, this Court should reject significance testing as the sole acceptable criterion of scientific validity in epidemiology. Just as the lexicon of the epidemiologist should be improved by expunging references to statistical significance, that term should be removed from the inappropriate legal pedestal, remote and separate from reality, on which it was placed by the lower courts.

II. THE APPELLATE COURT'S SKEPTICISM ABOUT "REANALYSIS" IS UNFOUNDED AND FORECLOSES EXPERTS FROM DRAWING INFERENCES FROM ALL AVAILABLE INFORMATION

A. "Reanalysis" is a Generally Accepted Methodology Within Science, Including in the Field of Epidemiology

The suggestion of the appellate court to the contrary, "reanalysis" in regards to epidemiology is not foreign to epidemiology, but essential to it -- for it is the principal mode of the "replication" that is fundamental to science and so lauded by the appellate court. "Replicating" is the process by which one scientist tries to verify the procedures and analyses undertaken by other scientists. In some disciplines, such as chemistry and subatomic physics, it is possible to replicate from scratch the exact experiment conducted by the first scientist. In other situations, the expense involved, or the existence of ethical constraints, limits the second scientist only to analysis of the data

accumulated by the first scientist or by other scientists; new data cannot be collected. For example, an epidemiologist is not in a position to expose a million workers to asbestos, or a million women to DES, to test the etiology of diseases caused by these products. An epidemiologist in such cases is restricted to studying the information available, no matter how limited, and inevitably must engage in "reanalysis" of existing data.

In an apparent effort to devise a bright-line rule, the court below has erected a false dichotomy. According to the appellate court, "analysis" takes place when an epidemiologist collects his or her own underlying data and develops inferences from it, and publishes or otherwise circulates the study, whereas "reanalysis" occurs whenever any other scientist looks at that study, alone or in combination with other published articles or other non-published studies, and expresses his or her own inferences from the larger universe of data. The appellate court's suggestion that reanalysis of epidemiological studies is something unusual, deserving more than other scientific techniques to be scrutinized skeptically, is simply wrong. In fact, reanalysis, even as defined by the lower court, is not an arcane or specialized enterprise; rather, this is the everyday work of the practicing epidemiologist in fields of public health.

In analyzing all available data and evaluating different theories that might explain such data, scientists not only assay the conventional wisdom but the unorthodox wisdom as well. By contrast, implicit in the appellate court's holding is that when the *conclusion* of an epidemiologist from a body of data differs from that reached by another epidemiologist who has published his or her conclusions, something unusual is occurring, and that the dissenting epidemiologist's views are inherently suspect. This is a dangerous course because it risks shutting off serious inquiry into important scientific issues at a superficial level. For example, the appellate court opines that the methodology of "reanalysis" is "particularly problematic in light of the massive weight of the original published studies supporting the defendant's position, all of which had undergone full scrutiny from the scientific community." *Daubert v. Merrell Dow*

Pharmaceuticals, Inc., 951 F.2d 1128, 1130 (9th Cir.1991). This "massive weight" is thought to flow from the fact that "no published epidemiological study had demonstrated a statistically significant association between Bendectin and birth defects." *Id.* at 1129.

Without expressing a position on the ultimate issue of the toxicity of Bendectin, it is obvious to us that no "massive weight" or sense of consensus can flow from the observation that a number of studies have been published involving Bendectin and that the authors of those studies did not infer *a "statistically significant association."* To give weight to the failure of epidemiological studies to meet strict "statistical significant" standards -- to use such studies to close the door on further inquiry -- is not good science. In fact, as discussed in Part I, it is both bad science and bad policy. *Amici* respectfully incorporate the positions as set forth in Section I, *supra*, as to why mindless adherence to significance testing is bad science.

B. The analysis employed by the lower courts forecloses the use of valid inferences that may be drawn from the combination of many studies, even when none of the studies standing alone would justify such inferences.

Empirical research quite often yields data that suggest an association between a suspected risk factor and a medical condition, but with too small a data set to proclaim confidently that the observed association is real, and not merely the result of random factors. If the observed association resulted by chance, one would not expect to see it consistently replicated in studies of similar scope. If, on the other hand, the observed association reflects a real relationship, one would expect to see consistent results in studies of similar scope.

This commonsense observation is not novel or controversial, yet the opinion of the appellate court forecloses analysis based on it. To the extent that the lower courts' opinion bars expert opinions not based on published conclusions, that

opinion removes relevant information from the legal decision maker. That valuable information would be lost by such an exclusion can easily be illustrated by reference to presidential election polls. Assume that two days before the election, several major polls showed the challenger leading the incumbent, but by margins that were within each poll's margin of error. That is, the challenger's lead, based on the sample of voters questioned by each pollster, was not "statistically significant" at the threshold level employed by those polls. Thus, each pollster declined to conclude, based on its own data, that the challenger was in the lead. Nonetheless, a rational observer, noting that the chasllenger had a similar lead in each poll, would conclude that he was, in fact, in the lead. Why? Because the observer has implicitly pooled the data to reach a conclusion that the separate pollsters, describing only their part of the data could not reach.

The lower courts' decisions would foreclose this analysis. As other courts have recognized, foregoing the benefit of inferences that could be reached this way is inappropriate:

> A word about our approach to the evidence may be in order. Contrary to the apparent suggestion of some of the petitioners, we need not seek a single dispositive study that fully supports the Administrator's determination. Science does not work that way; nor, for that matter, does adjudicatory factfinding. Rather, the Administrator's decision may be fully supportable if it is based, as it is, on the inconclusive but suggestive results of numerous studies. By its nature, scientific evidence is cumulative: the more supporting, albeit inconclusive evidence available, the more likely the accuracy of the conclusion. If, as petitioners suggest, one single study or bit of evidence were sufficient independently to mandate a conclusion, there would, of course, be not need for any other studies. Only rarely, however, is such a limited study sufficient. Thus, after considering the inferences that can be drawn from the studies supporting the Administrator, and those opposing

> him, we must decide whether the cumulative effect of all this evidence, and not the effect of any single bit of it, presents a rational basis for [the regulation in question].

Ethyl Corporation v. Environmental Protection Agency, 541 F.2d 1 (D.C. Cir. 1976) (*en banc*).

Thus, to the extent that the opinion of the appellate court would bar consideration of the cumulative effect of many studies, even when none of them individually is "statistically significant," it should be rejected on the basis that such a conclusion is scientifically inappropriate.

III. INFERENCES DRAWN FROM EPIDEMIOLOGIC REANALYSES ARE NOT SCIENTIFICALLY INVALID JUST BECAUSE THEY ARE NOT PUBLISHED IN PEER REVIEW JOURNALS

The appellate court is incorrect in suggesting that scientists have confidence in such "reanalysis," only if it is formally peer reviewed and published. To the contrary, only some of the conclusions drawn from such reanalyses are ever pul lished. Practicing scientists rely more often on informal exchange of papers, conversations, symposia, etc., in identifying new problems and in challenging consensus. Publication in peer-review journals obviously helps djsseminate those views further, and is an aid to a scientist's career (particularly in the academic arena), but peer-reviewed publications have never functioned as either reliable predictors or sole guarantors of scientific truth, as the appellate court seems to assume. It is the close and repeated questioning of all available scientific information on a given issue, and of the "accepted wisdom" on that issue, rather than consensus alone, that is the engine of scientific progress and the determinant of particular scientific truths. This is the type of "replication and verification" at the heart of "good science." Any decision maker responsible for resolving an issue of scientific fact should have available all sources of information that shed light on what may be considered the "consensus" view

in a given scientific field.

Were we on a jury in a civil trial, *amici* would wish to have access to the same sources we consult as practicing scientists. We would want to know all the facts, not just the truncated "consensus." The standard adopted by the appellate court would bar epidemiology experts from presenting to legal factfinders key information of the kind that on which they routinely rely on and communicate to other scientists in discharging important regulatory and other public health duties. Every new scientific idea, at its inception, is unpublished. These ideas may be nurtured through discussions, symposia and other means of communication without peer review publication. This is the way of science as it evolves towards, but never obtains, absolute truth.

CONCLUSION

The opinions of the trial court and the appellate court demonstrate a fundamental misunderstanding of the role and the function of epidemiology in contributing helpful information to complex scientific questions. *Amici* respectfully request that this Court re-establish appropriate standards and methodology consistent with the points as set forth in this brief.

Respectfully submitted,

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APPENDIX

IDENTIFICATION OF AMICI CURIAE

Dr. Rothman was born in New York City in 1945, and attended public schools in Long Beach, New York. His undergraduate studies were at Colgate University, and his graduate work was at Harvard University. After receiving his Doctor of Public Health degree from Harvard in 1972, Dr. Rothman remained at the Department of Epidemiology at Harvard for 12 years as a faculty member. During these years he conducted research on the epidemiology of cancer and birth defects; he also taught advanced courses and wrote numerous papers on epidemiologic concepts and methods. For five years he was Professor of Family and Community Medicine at the University of Massachusetts Medical School. Currently he holds academic appointments as Professor of Public Health (Epidemiology and Biostatistics) at the Boston University Schools of Medicine and Public Health, and Adjunct Professor of Epidemiology at the Harvard School of Public Health. He also serves as a Senior Epidemiologist at Epidemiology Resources Incorporated.

Dr. Rothman has given advanced courses in epidemiologic concepts and methods by invitation in many universities in the U.S. and abroad, and he teaches a popular course each summer at the New England Epidemiology Institute. He is the author of a textbook of epidemiologic methods, *Modern Epidemiology*, which was published in 1986 and is now in its fifth printing. He has served for 12 years as a member of the Editorial Board of the *New England Journal of Medicine*; he has also served as Assistant Editor of the *American Journal of Public Health* and as Editor of the *American Journal of Epidemiology*. He now devotes much of his professional effort to his duties as Editor of *Epidemiology*.

Dr. Weiss has been the Chairman of the Department of Epidemiology, School of Public Health and Community Medicine, University of Washington in Seattle, Washington since

July 1984. His undergraduate studies were at Stanford University, and he obtained an M.D. Degree at Stanford University in 1967. He received a Masters and Doctor of Public Health Degree at Harvard School of Public Health in 1969 and 1971, respectively. His field of study was Epidemiology. Following the completion of his education, he was an epidemiologist at the Office of Health Statistics Analysis, National Center for Health Statistics in Rockville, Maryland. For three years he was the Head of the Cancer Surveillance System Program in epidemiology and biostatistics at the Fred Hutchinson Cancer Research Center in Seattle, Washington. His research and writing in the field of epidemiology include a total of 185 publications. Since July, 1979, he has been a Professor in the Department of Epidemiology, School of Public Health and Community Medicine at the University of Washington.

During all of these years Dr. Weiss has conducted research on the epidemiology of various disease processes, including the relationship between occupation and the occurrence of testicular cancer, tubal sterilization and subsequent ectopic pregnancy, exogenous estrogens and the risk of endometrial cancer, the prevalence of diabetes and impaired glucose tolerance among Navajo Indians, risk factors for tubal infertility, to name but a few areas of research. He has also taught advanced courses and written numerous papers on epidemiologic concepts and methods. Additionally, he has received research grants in epidemiology and biostatistics and has been actively involved in the Fred Hutchinson Cancer Research Center, Seattle, Washington, since 1974, first as an Assistant Member (January, 1974-June, 1976), Associate Member (July, 1976-June, 1982), and Member (July, 1982-present).

Dr. Robins is a Professor of Epidemiology and Biostatistics at the Harvard School of Public Health. His undergraduate studies were at Harvard where he achieved distinction in mathematics (Phi Beta Kappa). He received his M.D. degree from Washington University School of Medicine in 1976. Dr. Robins was an Intern in Internal Medicine at Harlem Hospital Center, New York (1976-77), a Resident in the Department of

Internal Medicine at Yale University School of Medicine (1978-80), and a Fellow in Preventive Medicine, Department of Epidemiology and Public Health, Yale University School of Medicine (1980-81). He was an Associate Director, at the General Occupational Health Clinic, Yale University Department of Internal Medicine (1979-82). and a Consultant in Occupational and Environmental Health to the Connecticut State Department of Health Services (1981-83). Dr. Robins was an Assistant Professor of Biostatistics, Harvard School of Public Health (1986-87), Assistant Professor of Occupational Health, Harvard School of Public Health (1982-87) and Associate Professor of Occupational Health and Biostatistics, Harvard School of Public Health (1987-1992)

His research and writing in the fields of biostatistics and epidemiology include a total of 51 publications. Many of these papers dealt with advanced concepts and methods in epidemiology. Dr. Robins is board certified in Internal Medicine (1980) and is a member of several organizations relevant to the fields of biostatistics and epidemiology. He has received grants as the Principal Investigator for various areas of biostatistics research. He has taught advanced courses in epidemiologic methods and occupational and environmental epidemiology at the Harvard School of Public Health. He serves as an Associate Editor for the *American Journal of Epidemiology*.

Dr. Neutra was born in Los Angeles in 1939. He received his B.A. degree at Pomona College, Claremount, California (1961), M.D., C.M. at McGill, Faculty of Medicine, Montreal (1965), and interned at Royal Victoria Hospital, Montreal (1965-66). He received his M.P.H. (1969) and Dr.P.H. (1974) from the Harvard School of Public Health. Between 1970-1973 he served as a Research Fellow at the International Center for Medical Research and training, Cali, Colombia (Tulane University). During those same years he was a Research Fellow at the Harvard School of Public Health. In 1972-73, he was a Visiting Assistant Professor in Epidemiology, in the Department of Social Medicine, Universidad del Valle, Cali, Colombia. Between 1973-75, Dr. Neutra was an Instructor in the Department of Preventive and Social Medicine at Harvard

Medical School and a Visiting Lecturer, Spanish Epidemiology, Course for Professors of preventive Medicine, Federations of Pan American Faculties of Medicine, Bogota, Mexico City. He served as an Assistant Professor, Department of Epidemiology from 1974-1977 at the Harvard School of Public Health and from 1975-1977 as Assistant Professor, Department of Preventive and Social Medicine, Harvard Medical School. He became an Associate Professor, Division of Epidemiology, UCLA School of Public Health and Director, UCLA-Milbank, Program in Epidemiology and Health Policy (1977-1980). He was Associate Professor, Department of Medicine, UCLA Medical School (1978-1980) and Associate Director for Research, Center for Health Enhancement, Education and Research, UCLA Medical School (1978-1979). In 1980-1981, he served as Senior Epidemiologist, Epidemiological Studies Section, California Department of Health Services and has served as Lecturer in Epidemiology, University of California School of Public Health from 1981 to present. He served as Chief, Special Epidemiological Studies Program, California Department of Health Services from 1981-1982 and Chief, Exposure Assessment Section, California Department of Health Services from 1992 to present.[4] Additionally, he is currently Acting Chief, Environmental Health Investigations Branch, California Department of Health Services. Dr. Neutra is a past President of the International Society for Environmental Epidemiology, a member of the American College of Epidemiology, the International Society of Exposure Assessment, the American Epidemiological Society, International Epidemiological Association, Society for Epidemiologic Research and the American Public Health Association. He is board certified in Preventive Medicine, a Diplomate of the National Board of Medical Examiners and a Licentiate of the Medical Council of Canada. He has written many articles in the field of Epidemiology and Preventive Medicine with an emphasis in evaluation of medical technology, decision analysis, and

[4] Dr. Neutra is appearing as amicus in his own behalf and not as a representative of any governmental agency.

environmental epidemiology as applied to regulatory decisions.

Dr. Stellman received his B.Sc. in chemistry from Ohio State University in 1966, his Ph.D. in physical chemistry from New York University in 1971, and an M.P.H. in health policy and management from Columbia University in 1992. He was also a post-doctoral fellow in biochemical sciences at Princeton University in 1971-3 and Lecturer in Chemistry at the University fo Colorado at Denver in 1974. From 1975-80 he was Chief, Division of Computing and Biostatistics with the American Health Foundation in New York, where he directed numerous epidemiological studies of cancer with respect to environmental and lifestyle factors.

From 1980 through 1988 he was Assistant Vice President for Epidemiology with the American Cancer Society's national office, where he was Associate Director of Cancer Prevgention Study II, a six-year prospective study of mortality in 1.2 million American men and women and the largest such epidemiological study ever undertaken. In 1988 he became Assistant Commissioner of Health for Biostatistics and Epidemiologic Research for the City of New York, with administrative responsibility for registration of births and deaths, and as Director of the Bureau of Vital Statistics had scientific responsibility for records-based research on birth outcomes, such as birth defects. As Assistant Commissioner he was also editor-in-chief of *New York City Vital Statistics*, and had responsibility for the Office of Epidemiologic Research. During this period he directed studies in numerous areas of epidemiology, including infectious and chronic diseases, tuberculosis, prison health, cancer and the environment, maternal and child health, and AIDS.

In 1991 he returned to the American Health Foundation as a Senior Research Scientist where he is the chief epidemiologist for studies of tobacco-related cancers. He is also working at the International Agency for Research on Cancer in Lyon, France, as an NIH Fogarty International Fellow studying cancer in Asian immigrants to New York City. He has recently completed a master's degree in public health at Columbia University.

Dr. Stellman has published over sixty papers in epidemiology and health sciences, and another twenty-six in biophysical chemistry. He is a member of numerous professional associations,

including the American College of Epidemiology, Society of Epidemiologic Research, and American Chemical Society. He has been on the adjunct medical faculties of Cornell University adn the University of Pennsylvania, and is currently Adjunct Associate Professor of Community Medicine at the Mount Sinai School of Medicine in New York. He is Associate Editor of the peer-reviewed journal *Women and Health*, and is on the Advisory Board of the Public Health Graduate Program of the Robert Wood Johnson School of Medicine/University of Medicine and Dentistry of New Jersey. Dr. Stellman is an Exposure Consultant to the U.S. Federal District Court (Brooklyn) Agent Orange Veteran Payment Program and has served on numerous governmental and private scientific advisory committees, including the National Academy of Sciences Committee on Carcinogenicity of Cyclamate. He has received citations for public service from the American Legion and from the Vietnam Veterans of America.

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IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and As Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and As Guardian Ad Litem for ERIC SCHULLER,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF *AMICI CURIAE* OF THE STATES OF TEXAS, MONTANA, IDAHO, AND SOUTH DAKOTA, IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI*

Amici Curiae, the States of Idaho, Montana, South Dakota and Texas, file this brief to urge this Court's most careful attention to the important State interests threatened by the Ninth Circuit's holding below that the "general acceptance" test of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), may be used to exclude scientific evidence in federal civil litigation. *Daubert v. Merrell Dow Pharmaceuticals, Inc* , 951 F.2d 1128 (9th Cir. 1991). An affirmance of any use of *Frye* in diversity cases like this one, raising garden-variety tort and contract issues arising solely under state law, would have a significant adverse effect on the substantive law of the States. At least 45 States decline to impose on plaintiffs in civil cases any special burden of making a threshhold showing that their scientific testimony enjoys general acceptance. Therefore, use of the judge-made *Frye* rule where the law of these States controls would plainly violate the doctrine of *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938).

ARGUMENT

It would appear that *any* use of the *Frye* rule to exclude evidence in federal court is ruled out by Fed. R. Evid. 402, which lists all sources of rules for excluding relevant evidence but fails to include among those sources judge-made exclusionary doctrines in general, and *Frye* in particular. If, despite Rule 402, this Court were to conclude that it has some discretion to adopt the *Frye* rule for use in federal litigation, *amici* urge that *Frye* be strictly limited to the federal criminal law context in which it has been traditionally employed for decades by the lower federal courts.

This Court has never ratified use of the *Frye* test, but the lower federal courts have long employed it, leading to dozens of reported appellate opinions. The overwhelming proportion of federal appellate cases analyzing the admissibility of scientific evidence under *Frye* — sixty-six reported cases in all — have

reviewed criminal trials.[1] *Frye* has traditionally been understood

[1] *United States v. Todd*, 964 F.2d 925, 930-31 (9th Cir. 1992); *United States v. Jakobetz*, 955 F.2d 786 (2nd Cir. 1992), *cert. denied*, 121 L.Ed.2d 63 (1992); *United States v. Lopez-Navalles*, 931 F.2d 898 (9th Cir. 1991); *United States v. Hadley*, 918 F.2d 848, 853 (9th Cir. 1990), *cert. dismissed*, No. 91-6646, 1992 U.S. LEXIS 7341; *United States v. Two Bulls*, 918 F.2d 56, 57-62 (8th Cir. 1990), *reh'g granted, vacated, en banc*, 925 F.2d 1127 (1991); *United States v. Boise*, 916 F.2d 497, 503 (9th Cir. 1990), *cert. denied*, 111 S.Ct. 2057 (U.S. 1991); *United States v. Piccinonna*, 885 F.2d 1529, 1530-37 (11th Cir. 1989); *United States v. Smith*, 869 F.2d 348, 349-54 (7th Cir. 1989); *United States v. Gillespie*, 852 F.2d 475, 480-81 (9th Cir. 1988); *Bundy v. Dugger*, 850 F.2d 1402 (11th Cir. 1988), *reh'g denied en banc*, 859 F.2d 928 (1988), *cert. denied*, 488 U.S. 1034 (1988) (habeas case); *Little v. Armontrout*, 835 F.2d 1240, 1241-45 (8th Cir. 1987), *cert. denied*, 487 U.S. 1210 (1988) (habeas case); *U.S. v. Christophe*, 833 F.2d 1296, 1297-1300 (9th Cir. 1987); *Little v. Armontrout*, 819 F. 2d 1425, 1426-35 (8th Cir. 1987) (habeas case); *United States v. Kozminski*, 821 F.2d 1186, 1193-95, 1198-1219 (6th Cir. 1987); *United States v. Shorter*, 809 F.2d 54, 58-61 (D.C. Cir. 1987), *cert. denied*, 484 U.S. 817 (1987); *United States v. Kimberlin*, 805 F.2d 210, 216-23 (7th Cir. 1986), *cert. denied*, 483 U.S. 1023 (1987); *United States v. Gwaltney*, 790 F.2d 1378, 1381-83 (9th Cir. 1986), *cert. denied*, 479 U.S. 1104 (1987); *United States v. Darcy*, 783 F.2d 1389, 1391, 1394-97 (9th Cir. 1986); *United States v. McBride*, 786 F.2d 45, 49-50 (2nd Cir. 1986); *United States v. Metzger*, 778 F.2d 1195, 1203-1204 (6th Cir. 1985), *cert. denied*, 477 U.S. 906 (1986); *United States v. Ferri*, 778 F.2d 985, 988-90 (3rd Cir. 1985), *cert. denied*, 476 U.S. 1172 (1986); *United States v. Smith*, 776 F.2d 892, 898 (10th Cir. 1985); *United States v. Davis*, 772 F.2d 1339, 1341-47 (7th Cir. 1985), *cert. denied*, 474 U.S. 1037 (1985); *United States v. Solomon*, 753 F.2d 1522, 1523-1526 (9th Cir. 1985); *United States v. Downing*, 753 F.2d 1224, 1226-44 (3rd Cir. 1985); *United States v. Gould*, 741 F.2d 45, 48 (4th Cir. 1984); *United States v. Torniero*, 735 F.2d 725, 731 (2nd Cir. 1984), *cert. denied*, 469 U.S. 1110 (1985); *United States v. Valdez*, 722 F.2d 1196, 1200-05 (5th Cir. 1984); *United States v. Lewellyn*, 723 F.2d 615, 618-20 (8th Cir. 1983); *United States v. Fleishman*, 684 F.2d 1329, 1336-37 (9th Cir. 1982); *United States v. Black*, 684 F.2d 481, 482-84 (7th Cir. 1982), *cert. denied*, 459 U.S. 1043 (1982); *United States Ex Rel. DiGiacomo v. Franzen*, 680 F.2d 515, 516-20 (7th Cir. 1982); *United States v. Tranowski*, 659 F.2d 750, 751-57 (7th Cir. 1981); *United States v. McFillin*, 713 F.2d 57, 58-61 (4th Cir. 1981), *cert. denied*, 454 U.S. 1057 (1981); *McMorris v. Israel*, 643 F.2d 458, 459-66 (7th Cir. 1981),*cert. denied*, 455 U.S. 967 (1982) (habeas case); *United States v. Distler*, 671 F.2d 954, 960-62 (6th Cir. 1981), *cert. denied*, 454 U.S. 827 (1981); *United States v. Clark*, 622 F.2d 917 (5th Cir. 1980), *cert. denied*, 449 U.S. 1128 (1981); *United States v. Fosher*, 590 F.2d 381, 383 (1st Cir. 1979); *United States v. Williams*, 583 F.2d 1194, 1196-1201 (2nd Cir. 1978), *cert. denied*, 439 U.S. 1117 (1979); *Hughes v. Mathews*, 576 F.2d 1250, 1258 (7th Cir. 1978), *cert. dismissed sub nom., Isreal v. Hughs*, 439 U.S. 801 (1978) (habeas case);

as a doctrine governing criminal trials, predicated on concern about the special impact that novel forms of scientific investigation might have in criminal litigation, given the stakes involved. For example, the leading scholarly article on the *Frye* rule, published in 1980, is devoted to the many ramifications of *Frye* for criminal law, and does not discuss the use of *Frye* in civil cases. *See* Paul C. Giannelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half Century Later*, 80 Colum. L. Rev. 1197 (1980).

One function of *Frye* is to ensure that the value of novel forensic techniques can be intelligently contested by both sides in a criminal trial: "the *Frye* test protects prosecution and defense alike by assuring that a minimal reserve of experts exists who can critically examine the validity of a scientific determination in a particular case." *United States v. Addison*, 498 F.2d 741, 743

United States v. Kilgus, 571 F.2d 508, 508-10 (9th Cir. 1978); *United States v. Bad Cob*, 560 F.2d 877, 881-84 (8th Cir. 1977); *United States v. McDaniel*, 538 F.2d 408, 412-14 (D.C. Cir. 1976); *United States v. Alexander*, 526 F.2d 161, 162-70 (8th Cir. 1975); *United States v. Oliver*, 525 F.2d 731, 733-37 (8th Cir. 1975), *cert. denied*, 424 U.S. 973 (1976); *United States v. Marshall*, 526 F.2d 1349, 1360 (9th Cir. 1975), *cert. denied*, 426 U.S. 923 (1976); *United States v. Carter*, 522 F.2d 666, 684-86 (D.C. Cir. 1975); *United States v. Baller*, 519 F.2d 463, 464-67 (4th Cir. 1975), *cert. denied*, 423 U.S. 1019 (1975); *United States v. Franks*, 511 F.2d 25, 33 (6th Cir. 1975), *cert. denied*, 422 U.S. 1042 (1975); *United States v. Cochran*, 499 F.2d 380, 393 (5th Cir. 1974), *cert. denied*, 419 U.S. 1124 (1975); *United States v. Addison*, 498 F.2d 741, 741-45 (D.C. Cir. 1974); *United States v. Skeens*, 494 F.2d 1050, 1053 (D.C. Cir. 1974); *United States v. Amaral*, 488 F.2d 1148, 1152-53 (9th Cir. 1973); *United States v. Frogge*, 476 F.2d 969, 969-70 (5th Cir. 1973), *cert. denied*, 414 U.S. 849 (1973); *United States v. De Betham*, 470 F.2d 1367, 1368 (9th Cir. 1972), *cert. denied*, 412 U.S. 907 (1973); *United States v. Alexander*, 471 F.2d 923, 955 (D.C. Cir. 1972), *cert. denied sub nom.*, Murdock v. United States, 409 U.S. 1044 (1972); *United States v. Parman*, 461 F.2d 1203, 1204-05 (D.C. Cir. 1971); *United States v. Brown*, 461 F.2d 134, 145 (D.C. Cir. 1972); *United States v. Stifel*, 433 F.2d 431, 435-41 (6th Cir. 1970), *cert. denied*, 401 U.S. 994 (1971); *United States v. Tremont*, 351 F.2d 144, 146 (6th Cir. 1965), *cert. denied*, 383 U.S. 944 (1966); *McCroskey v. United States*, 339 F.2d 895, 897 (8th Cir. 1965); *United States v. McDevitt*, 328 F.2d 282, 283-84 (6th Cir. 1964); *Marks v. United States*, 269 F.2d 377, 382 (10th Cir. 1959); *Lindsey v. United States*, 237 F.2d 893, 894-96 (9th Cir. 1956); *Tyler v. United States*, 193 F.2d 24, 31 (D.C. Cir. 1951), *cert. denied*, 343 U.S. 908 (1952); *Medley v. United States*, 155 F.2d 857, 860 (D.C. Cir. 1946), *cert. denied*, 328 U.S. 873 (1946).

(D.C. Cir. 1974). But *Frye* is not entirely even-handed: its rationale stems largely from a desire to guard against possible unfairness to defendants, by placing additional burdens on the prosecution when novel scientific evidence is offered. *See, e.g., United States v. Brown*, 557 F.2d 541, 556 (6th Cir. 1977) ("A courtroom is not a research laboratory. The fate of a defendant in a criminal prosecution should not hang on his ability to successfully rebut scientific evidence which bears an 'aura of special reliability and trustworthiness,' although, in reality the witness is testifying on the basis of an unproved hypothesis in an isolated experiment which has yet to gain general acceptance in its field"); *United States v. Fleishman*, 684 F.2d 1329, 1337 (9th Cir.), *cert. denied*, 459 U.S. 1044 (1982) (*Frye* rule flows from a "concern[] with the possible prejudice to the defendant's right to a fair trial of admitting testimony of purported experts based upon insufficiently substantiated scientific theories, techniques or tests"); Giannelli, *supra*, at 1244 ("The underlying problem is that the 'burden of rebuttal is generally borne in these criminal cases by defendants without the economic means to marshal scientific witnesses for a battle of the experts'") (citation omitted).

If the policy assumptions animating the *Frye* test are in fact well founded, then *Frye* and its progeny in the lower federal courts may be a proper exercise of the supervisory power over criminal cases. Long ago this Court recognized that "[j]udicial supervision of the administration of criminal justice in the federal courts implies the duty of establishing and maintaining civilized standards of procedure and evidence." *McNabb v. United States*, 318 U.S. 332, 340 (1943). Whether or not this Court is inclined to uphold the *Frye* doctrine in federal criminal trials on this basis, the past use of *Frye* in the criminal context lends no legitimacy to the use of *Frye* to impose a special judge-made rule for scientific evidence for *civil* trials, particularly trials in which state law supplies the rule of decision.

Indeed, perhaps in recognition of these principles, *Frye* has almost never been applied by the federal appellate courts to uphold exclusion of evidence in a civil trial. In each of the few instances in which it was applied, the appellate court failed to

provide any rationale for extending *Frye* into the civil arena. In 1984, the Fifth Circuit employed *Frye* to overturn a district court's admission of a type of "voice stress analysis" in a civil diversity case involving an insurance claim; in support, the court cited only federal criminal cases relying on *Frye*, and wholly failed to consider the propriety of imposing *Frye* in a civil case. *See Barrel of Fun, Inc. v. State Farm Fire & Cas. Co.*, 739 F.2d 1028, 1031 (5th Cir. 1984). Seven years later, the Fifth Circuit again employed *Frye* in a civil diversity case, again without providing any justification for doing so, to exclude the testimony of a qualified medical expert on the cause of a rare form of cancer, on the ground that the expert's reasoning was not "generally accepted." *See Christophersen v. Allied Signal Corp.*, 939 F.2d 1106, 1115-16 (5th Cir.) (per curiam) (en banc), *cert. denied*, 112 S. Ct. 1280 (1991). The Ninth Circuit decision below is only the third federal appellate decision to use *Frye* to exclude evidence in a diversity case; again, no rationale for extending *Frye* beyond the criminal context involving due process and supervisory powers was provided. *See Daubert*, supra, 951 F.2d at 1129-30.

An affirmance by this Court of the Ninth Circuit's application of *Frye* in a civil diversity case would attack the integrity of the substantive law of the States and would read the Federal Rules of Evidence in a way that States could not have envisioned in 1975 — preventing the political safeguards of federalism from operating. The States have chosen to provide their citizens with private causes of action, under statute and common law, through which they may receive compensation for harms caused by toxic substances and defective products, and thereby also to deter similar future harms. Inherently, such claims impose on plaintiffs the difficult task of establishing such complex facts as dangerousness and causation — matters that almost inevitably require the presentation of scientific evidence. How such issues are proven, and what types of evidence are sufficient to permit recovery, are part and parcel of the States' policy judgment as to the nature and scope of the cause of action. To demand that plaintiffs present the testimony of experts whose form of reasoning about standard sources of information meets

a "rigorous standard" that includes all elements of "generally accepted scientific methodology," including peer review and publication, *Daubert*, *supra*, 951 F.2d at 1131, is to impose a significant burden to recovery that *no State* currently imposes on plaintiffs in state court. In brief:

• Twenty-five States have declined to adopt the *Frye* "general acceptance" test, have rejected it, or do not use it to the exclusion of other tests in ruling on the admissibility of novel scientific evidence in criminal or quasi-criminal cases (such as paternity suits).[2]

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[2] **Arkansas**: *Prater v. State*, 820 S.W.2d 429, 431 (Ark. 1991) ("courts may look to a number of other factors which bear upon reliability").

Colorado: *People v. Hampton*, 746 P.2d 947, 950-51 (Colo. 1987).

Delaware: *Santiago v. State*, 510 A.2d 488, 489 (Del. 1986) ("*Frye* 'general acceptance' test is not the sole test for judging admissibility of expert testimony concerning scientific test results in Delaware").

Florida: *Andrews v. State*, 533 So. 2d 841 (Fla. Dist. Ct. App. 1988), rev. denied, 542 So. 2d 1332 (Fla. 1989) (relevancy test should be applied rather than Frye general acceptance test).

Georgia: *Caldwell v. State*, 393 S.E. 2d 436, 441 (Ga. 1990); *Harper v. State*, 292 S.E.2d 389, 395-96, (Ga. 1982) ("the *Frye* rule of 'counting heads' in the scientific community in not an appropriate way to determine the admissibility of a scientific procedure in evidence," id. at 395).

Hawaii: *State v. Montalbo*, 828 P.2d 1274, 1279-81 (Hawaii 1992) (*Frye* "general acceptance" standard is only one of several factors to be weighed in determining whether scientific evidence is reliable and should be admitted).

Idaho: *State v. Rodgers*, 812 P.2d 1208, 1210-12 (Idaho 1991); *State v. Crea*, 806 P.2d 445, 448 (Idaho 1991).

Iowa: *State v. Murphy*, 451 N.W.2d 154, 156 (Iowa 1990).

Louisiana: *State v. Catanese*, 368 So.2d 975, 978-81 (La. 1979) ("[c]learly, the criteria used for determining the admissibility of scientific evidence should not require the instant and unquestionable demonstration required for the judicial notice of scientific facts").

Maine: *State v. LeBlanc*, 559 A.2d 349, 351 (Me. 1989); *State v. Williams*, 388 A.2d 500, 502-04 (Me. 1978) ("there is no justifiable distinction in principle arising becuase such expert testimony may happen to involve newly ascertained or newly applied scientific principles").

Montana: *State v. Walters*, 806 P.2d 497, 501 (Mont. 1991); *Barmeyer v. Montana Power Co.*, 657 P.2d 594, 598 (Mont. 1983) ("the general acceptance rule is not in conformity with the spirit of the new rules of evidence").

Nevada: *Santillanes v. State*, 765 P.2d 1147, 1150 n. 3 (Nev. 1988) ("In the sixty-five years since *Frye* was decided we have neither cited to nor adopted the decision").

• The bulk of the remaining States, twenty in all, do apply the *Frye* approach in at least some criminal or quasi-criminal cases but, as with the overwhelming precedent at the federal appellate level, do not employ *Frye* in civil cases.[3]

North Carolina: *State v. Pennington*, 393 S.E.2d 847, 852 (N.C. 1990); *State v. Bullard*, 322 S.E.2d 370, 380 (N.C. 1984) ("our court does not adhere exclusively to the *Frye* formula").

North Dakota: *State v. Brown*, 337 N.W.2d 138, 148, 148 n. 6 (N.D. 1983).

Ohio: *State v. Williams*, 446 N.E.2d 444, 446-48 (Ohio 1983) ("we refuse to engage in scientific nose-counting for the purpose of deciding whether evidence based on newly ascertained or applied scientific priciples is admissible").

Oregon: *State v. Brown*, 687 P.2d 751, 755-60 (Or. 1984) (rejecting *Frye* "general acceptance" test and adopting a seven-factor "relevancy" test to determine the relevance or probative value of proffered scientific evidence).

Rhode Island: *State v. Wheeler*, 496 A.2d 1382, 1388-89 (R.I. 1985).

South Carolina: *State v. Ford*, 392 S.E.2d 781, 783 (S.C. 1990) (accepting DNA evidence) ("South Carolina has never specifically adopted the *Frye* test and has employed a less restrictive standard in regard to the admissibility of scientific evidence").

Tennessee: *State v. Johnson*, 717 S.W.2d 298, 303 (Tenn. Crim. App. 1986) ("the modern trend, expressed in the Federal Rules of Evidence, is away from the *Frye* test").

Texas: *Kelly v. State*, 824 S.W.2d 568, 570-72 (Tex. Crim. App. 1992) (rejecting *Frye* standard and applying relevancy standard).

Utah: *State v. Tuttle*, 780 P.2d. 1203, 1211 n.8 (Utah 1989), *cert. denied*, 494 U.S. 1018 (1990).

Virginia: *O'Dell v. Commonwealth*, 364 S.E.2d 491, 504 (Va. 1988) (declining to adopt *Frye* standard).

West Virginia: *State v. Woodall*, 385 S.E.2d 253, 259-60 (W. Va. 1989).

Wisconsin: *State v. Blair*, 473 N.W.2d 566, 572 n. 9 (Wis. Ct. App.1991), *review denied*, 477 N.W.2d 287 (1991); *State v. Walstad*, 351 N.W.2d 469, 485-87 (Wis. 1984) ("The *Frye* concept is alien to the Wisconsin law of evidence.").

Wyoming: *Rivera (Kerry) v. State*, No. 90-163, 1992 WL 312899, at *7 (Wyo. Oct. 30, 1992) (subject to revision or withdrawal) (rejecting *Frye* and relying on Rule 702 standard).

[3] **Alabama**: *Adams v State*, 484 So.2d 1160, 1162 (Ala. Crim. App. 1985) (*Frye* test used to exclude expert testimony based on information obtained through hypnotic means); *Prewitt v. State*, 460 So.2d 296, 301-304 (Ala. Crim. App. 1984) ("In appropriate cases, Alabama follows the rule in

Frye," *id.* at 301); *but cf. Sexton v. State*, 529 So.2d 1041, 1049 (Ala. Crim. App.1988) (*Frye* not applied where factors of necessity, reliability, understandability, and importance dictated the admissibility of physician's expert testimony on behavior of child abuse victims).

Alaska: *Contreras v. State*, 718 P.2d 129, 134-36 (Alaska 1986); *Beagel v. State*, 813 P.2d 699, 707-8 (Alaska Ct. App. 1991).

California: *People v. Kelly* 549 P.2d 1240, 1244-46, 1250-51 (Cal. 1976) (using Frye to reject voiceprint analysis); but *cf. People v. McDonald*, 690 P.2d 709, 723-24 (Cal. 1984) (distinguishing between expert testimony and scientific evidence and holding *Kelly-Frye* rule inapplicable to expert testimony on eyewitness identification).

Connecticut: *State v. Miller*, 522 A.2d 249, 260 (1987); *State v. Atwood*, 479 A.2d 258, 263-64 (1984).

District of Columbia: *Jones v. United States*, 548 A.2d 35, 39-47 (D.C. App. 1988).

Illinois: *People v. Eyler*, 549 N.E.2d 268, 285-86 (Ill. 1989), cert. denied, 111 S.Ct. 215 (U.S. 1990); *People v. Milone*, 356 N.E.2d 1350, 1356-59 (Ill. App. Ct. 1976).

Indiana: *People v. Baynes*, 430 N.E.2d 1070, 1074-1079 (Ind. 1983) (citing *Frye* in excluding polygraph evidence but not explicitly adopting *Frye* test); *cf. Hopkins v. State*, 579 N.E.2d 1297, 1305-06 (Ind. 1991) (concurring opinion suggesting that *Frye* has not been conclusively adopted).

Kansas: *State v. Witte*, 836 P.2d 1110, 1116-21 (Kan. 1992); *Smith v. Deppish*, 807 P.2d 144, 157-59 (Kan. 1991); *State v. Washington*, 622 P.2d 986, 991-92 (Kan. 1981).

Kentucky: *Perry v. Commonwealth*, 652 S.W. 2d 655, 661 (Ky. 1983).

Maryland: *Cobey v. State*, 533 A.2d 944, 946-50 (Md. Ct. Spec. App. 1987), *cert. denied*, 538 A.2d 778 (1988); *Reed v. State*, 391 A.2d 364, 368-77 (Md. 1978).

Massachusetts: *Commonwealth v. Curnin*, 565 N.E.2d 440, 443 (Mass. 1991); *Commonwealth v. Fatalo*, 191 N.E.2d 479, 479-81 (Mass. 1963).

Minnesota: *State v. Fenney*, 448 N.W.2d 54, 57-58 (Minn. 1989); *State v. Mack*, 292 N.W.2d 764, 767-68 (Minn. 1980) (hypnotically induced testimony inadmissible under *Frye* standard).

Mississippi: *Goodson v. State*, 566 So.2d 1142, 1146 (Miss. 1990) (citing a general acceptance test but not citing *Frye* by name).

Nebraska: *State v. Reynolds*, 457 N.W.2d 405, 417-18 (Neb. 1990).

New Hampshire: *State v. Stewart*, 364 A.2d 621, 623 (N.H. 1976) (excluding polygraph evidence); *State v. Coolidge*, 260 A.2d 547, 560-61 (N.H. 1969), *cert. rev'd on other grounds*, 90 S.Ct. 2253 (1970).

New Mexico: *State v. Blea*, 681 P.2d. 1100, 1103 (1984).

Oklahoma: *Rawlings v. State*, 740 P.2d 153, 161 (Okla. Crim. App. 1987); *Driskell v. State*, 659 P.2d 343, 356 (Okla. Crim. App. 1983).

Pennsylvania: *Commonwealth v. Rodgers*, 605 A.2d 1228, 1234-35 (Pa. Super. Ct. 1992); *Commonwealth v. Nazarovitch*, 436 A.2d 170, 172-73 (Pa. 1981).

South Dakota: *State v. Adams*, 418 N.W.2d 618, 620 (S.D.1988); *State v. Helmer*, 278 N.W.2d 808, 812 (S.D. 1979).

Washington: *State v. Ortiz*, 831 P.2d 1060 (Wash. 1992).

• A handful of States have applied the *Frye* approach in at least some civil (as well as criminal) litigation, but appear to limit *Frye* to the traditional context of novel devices or procedures, and have never permitted its use in a civil case to scrutinize the reasoning of qualified expert witnesses based on standard sources of information in the relevant field.[4]

[4] **Arizona**: *Baroldy v. Ortho Pharmaceutical Corp.*, 760 P.2d 574, 581-82 (1987) (civil case refusing to apply *Frye* to the occlusion theory used as a basis for experts' opinion that a particular diaphragm caused toxic shock, explaining that "occlusion theory . . . is not the sort of 'procedure' or 'technique' to which the 'general acceptance' test of *Frye* is usually applied, but rather is a scientific hypothesis of causation"); *Troutman v. Valley National Bank of Arizona*, 826 P.2d 810, 815 (Arizona Ct. App. 1992) (civil case involving personal injury action by an injured party against the decedent's estate and admissibility of expert testimony on "thermogram" test results); *State ex rel. Collins v. Superior Court*, 644 P.2d 1266, 1285-95 (1982) (criminal case applying *Frye* to hypnosis).

Michigan: *Mulholland v. DEC Int'l Corp.*, 443 N.W.2d 340, 343 n.1 (Mich. 1989) (specific legislative adaptation of Rule 702 requires use of *Frye* standard in all cases); *People v. Marsh*, 441 N.W.2d 33, 34-36 (Mich. App. 1989) (admissibility of bite-mark analysis in a criminal case is not dependent on meeting *Davis-Frye* standard -- although idea of test is novel, the procedures and technology used to implement it are not).

Missouri: *Elam v. Alcolac, Inc.*, 765 S.W.2d 42, 189 n. 79 (Mo.App. 1988), *cert. denied*, 493 U.S. 817 (1989) (civil toxic tort case finding medical expert's methodology not to be excludable); *State v. Elbert*, 831 S.W.2d 646, 648 (Mo. Ct. App. 1992); *Alsbach v. Bader*, 700 S.W.2d 823, 828 (Mo. 1985); *State v. Stout*, 478 S.W.2d 368 (Mo. 1972).

New Jersey: *Windmere, Inc. v. International Ins. Co.*, 522 A.2d 405, 412 (N.J. 1987) (civil excluding expert testimony on voiceprints in case involving non-payment of insurance proceeds following arson); *but cf. Rubanick v. Witco Chemical Corp.*, 593 A.2d 733, 740-42, 746-48 (N.J. 1991) (rejecting "general acceptance" standard of *Windmere* and *Frye* in toxic tort cases); *Landrigan v. Celotex Corp.* 605 A.2d 1079, 1083-89 (N.J. 1992) (applying *Rubanick*). *See also State v. Hurd*, 432 A.2d 86, 89-92 (N.J. 1981) (criminal case setting standards for admissibility of post-hypnotic testimony).

New York: *Cameron v. Knapp*, 520 N.Y.S.2d 917, 918 (N.Y. 1987) (*Frye* standard used to bar handwriting analysis in medical malpractice action); *People v Mohit*, 579 N.Y.S.2d 990, 991-92 (N.Y. Co. Ct. 1992); *People v. Castro*, 545 N.Y.S.2d 985, 986-99, (N.Y. Sup. Ct. 1989) (creating "*Frye* plus" standard for DNA admissibility); *People v. Hughes*, 453 N.E.2d 484,

The approach to *Frye* embodied in the decision below therefore presents a classic violation of this Court's *Erie* jurisprudence. The Ninth Circuit's use of the *Frye* to require increased judicial scrutiny of a particular class of evidence — here, scientific evidence — is surely substantive within the meaning of *Dick v. New York Life Ins. Co.*, 359 U.S. 437, 446-47 (1959). *Frye* cannot survive in this civil diversity context to throw out a litigant's entire case merely because his or her expert testimony is not "generally accepted," because such a rule is exactly the type of rule *Erie* was meant to combat. The violation is especially clear here because *Frye* is, *at most*, a judge-made rule not required by any Act of Congress. *Cf. Guaranty Trust Co. v. York*, 326 U.S. 99, 110 (1945) (*Erie* requires adherence to any type of state rule having "consequences that . . . intimately affect recovery or non-recovery"). Outright dismissal of a case based on the *Frye* rule, where the case would have gone forward in state court, obviously effects inequitable administration of the laws and encourages rampant forum shopping, thereby violating both of the "twin aims" of the *Erie* doctrine. *See Chambers v. NASCO, Inc.*, 111 S.Ct. 2123, 2127 (1991); *Salve Regina College v. Russell*, 111 S. Ct. 1217, 1218 (1991). Moreover, it directly affects matters that are "bound up with" state-created rights and obligations. *See Byrd v. Blue Ridge Rural Elec. Coop., Inc.*, 356 U.S. 525 (1958).

The *Erie* problems that would be created by an affirmance by this Court were vividly sketched by the five judges who disagreed with the *en banc* majority in the recent Fifth Circuit *Christophersen* decision. One judge argued: "[I]f *Frye* is a rule of evidence, it has not survived the enactment of the Federal Rules of Evidence. . . . [I]f it is a substantive rule, its adoption in diversity cases is foreclosed by *Erie*." 939 F.2d at 1120 (Clark, J., concurring in the result) (citations omitted). Four other judges explained that to apply *Frye* to expert causation testimony was so decisive to the outcome of cases that its imposition "substantially affect[s] the rights of claimants and the

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490-97 (N.Y. 1984) (*Frye* standard applied to render victim's posthypnotic recollections inadmissible at defendant's rape trial).

proof required for their compensation." 939 F.2d at 1135 (Reavley, J., dissenting). These judges pointed out that "[u]nder Texas law, claimants [did] not suffer these disadvantages," and thus there was "no doubt that in Texas courts Mrs. Christophersen would have received her jury trial." *Id.* at 1135-36 & n.48. "This lack of congruence with the state courts in cases dependent on our diversity jurisdiction," these judges argued, "is fundamentally at odds with the Supreme Court's decision in *Erie*. As a result, we encourage reverse forum shopping and deprive plaintiffs of the substantive rights that should be available to them under state law." *Id.* at 1137-38 (King, J., dissenting).[5]

CONCLUSION

For these reasons, *amici* respectfully request this Court to reverse the decision below and to hold that, if the *Frye* rule has any remaining viability at all on the federal level, it may only be employed in criminal litigation.

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[5] Other federal appellate panels faced with requests similar to those in *Christophersen* to "screen out" particular kinds of evidence in diversity cases have recognized the *Erie* implications of such an effort, and have refused to permit judicial creation of "heightened scrutiny" in derogation of state law. In *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 952 (3d Cir. 1990), for example, the Third Circuit wrote that "we [are not] at liberty, *especially in a case to be decided under our diversity jurisdiction*, to impose different burdens of proof on Bendectin plaintiffs than those that would apply in analogous products liability suits." (Emphasis added). Similarly, the Fifth Circuit, relying in part on "the dictates of *Erie*, that we remain faithful to the law of Texas," rejected an attempt to create a special procedural framework designed to resolve in a single stroke a large class of asbestos cases. *In re Fibreboard Corp.*, 893 F.2d 706, 711 (5th Cir. 1990) (Higginbotham, J.).

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OCTOBER TERM, 1992

WILLIAM DAUBERT, *et al.*,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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BRIEF *AMICUS CURIAE* OF THE AMERICAN TORT REFORM ASSOCIATION IN SUPPORT OF RESPONDENT

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

No. 92-102

WILLIAM DAUBERT, *et al.*,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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BRIEF *AMICUS CURIAE* OF THE AMERICAN TORT REFORM ASSOCIATION IN SUPPORT OF RESPONDENT

INTEREST OF THE *AMICUS CURIAE* [1]

The American Tort Reform Association was established in 1986. It is a bipartisan coalition of approximately 400 non-profit organizations, professional societies, trade associations, corporations and small businesses, advocating improvements in the efficiency and fairness in the civil justice system. Members include the American Medical Association, the Council of Community Blood Centers, the National Association of Manufacturers, and a number of industrial corporations. ATRA has filed briefs *amicus curiae* in this and other courts in cases raising issues of significance to the functioning of the civil justice system. Some of ATRA's members are parties in civil actions in which the admissibility of particular opinion testimony is disputed. Three members (General Electric Company, Monsanto Company, and Southeastern Pennsylvania Transportation Authority)

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[1] Petitioners and respondent have consented to the filing of this brief; their letters to that effect have been lodged with the Clerk.

are defendants in pending litigation,[2] discussed herein, in which issues relating to the admissibility of expert opinion testimony have predominated.[3]

ATRA is concerned that appropriate standards govern the use of opinion testimony from experts. ATRA submits that, with or without the rule of *Frye* v. *United States*, 293 Fed. 1013 (D.C. Cir. 1923), this Court should reaffirm the broad and proper discretion of federal trial judges under the Federal Rules of Evidence to prohibit the use of opinion testimony that, although offered by a witness claiming scientific expertise, is not the product of scientific reasoning or is derived from a non-scientific methodology or is unsupported by an adequate factual foundation.

RULES INVOLVED

Rules 104(a), 401, 402, 403, 602, 701, 702, 703, 704 705, and 1101(d)(1) of the Federal Rules of Evidence are reproduced in the addendum hereto.

SUMMARY OF ARGUMENT

Witnesses in Anglo-American courts generally are not allowed to testify to their opinions. That is a rule centuries old, most recently embodied in Rules 602 and 701 of the Federal Rules of Evidence.

An exception to the rule is the "expert" witness. The qualified expert may offer opinions that are based on his or her field of expertise. There is a *quid pro quo*, however: the expert is to impart to the factfinder only the learning of the discipline in which the expert is credentialed. If the expert instead goes outside that field of expertise, or presents unsupported theories, or relies on methodologies alien to the discipline, then the expert

[2] *In re Paoli R.R. Yard PCB Litigation*, 706 F. Supp. 358 (E.D. Pa. 1988), *reversed*, 916 F.2d 829 (3d Cir. 1990), *cert. denied sub nom. General Electric Co.* v. *Knight*, 111 S. Ct. 1584 (1991), *on remand*, 1992 WL 315216 etc. (E.D. Pa. 1992), *appeals pending* (3d Cir. Nos. 92-1995 etc.).

[3] Respondent is owned by a company of which the majority of the stock is owned by an ATRA member, Dow Chemical Company.

is not speaking as the voice of that science and has become just an ordinary witness offering what in effect is lay opinion testimony or conjecture. Worse, the expert because he or she is titled as such, and invokes the jargon of science, is likely to command credence that a lay witness could not.

In the past two decades the need to confine experts to true expert opinions has been highlighted by the confluence of two trends. The first is the recent proliferation of a new kind of tort action that claims illness was caused by exposure to chemicals in tiny amounts not previously measurable—so-called "toxic tort" cases. The second is wide availability of some individuals, holding degrees in such disciplines as medicine, chemistry, or toxicology, who are willing to offer opinions that fly in the face of the findings, and ignore the methodology, of the very disciplines in which they are credentialed. In the words of one court, nowadays "there is not much difficulty in finding a medical expert witness to testify to virtually any theory of medical causation short of the fantastic." *Stoleson* v. *United States*, 708 F.2d 1217, 1222 (7th Cir. 1983). In some cases, even "the fantastic" has not been a barrier.[4]

The situation district judges most often encounter in civil litigation is not the expert who holds some sort of minority view on a topic undergoing scientific debate. Rather, what usually is offered is not novel science, but non-science. It is the expert who uses a degree—in medicine, for example—to gain entry to the courtroom, but then offers opinions that are not based on medical methods or reasoning at all. Some would call such a witness a charlatan. It is not necessary to judge the witness' motives or sincerity, however, to conclude that such a person

[4] *Cf., e.g., Sweger* v. *Texaco, Inc.*, 930 F.2d 35 (10th Cir. 1991) (expert "believed that Mr. Sweger's cancer could have been caused by exposure to a single carcinogenic molecule of defendant's motor oils") (text in Westlaw); *Tonkovich* v. *Department of Labor & Industries*, 31 Wash. 2d 220, 195 P.2d 638 (1948) (expert opinion that injury from fall caused cancer).

has gone beyond his or her credentials, and speaks not as the voice of science, but simply as an individual holding an opinion. Expert testimony should not be admissible when it consists of nothing but a resumé plus an assertion.

Most trial judges have been able to deal with such cases. They have considered themselves obliged by law to exclude such opinions from the evidence weighed by juries in deciding issues of liability. One formulation some courts follow, which is challenged by petitioners in this case, is that of *Frye* v. *United States*, 293 Fed. 1013 (D.C. Cir. 1923). As *Frye* put it, "while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery," still the basis for the opinion ("the thing from which the deduction is made") "must be sufficiently established to have gained general acceptance in the particular field." 293 Fed. at 1014.[5]

Unsupported opinions by experts are regularly excluded also in circuits that never adopted *Frye*. For with or without *Frye*, the Federal Rules of Evidence give ample authority—and, indeed, a responsibility—for trial judges to exclude such opinion testimony. Rule 104(a) directs that preliminary questions of admissibility "shall be determined by the court." Rules 401 and 402 direct the exclusion of evidence that is not relevant, defining relevance in a way that excludes speculation. Rules 602 and 701 prohibit most non-expert opinion. Rule 403 (which petitioners scarcely mention) specifically authorizes exclusion of evidence when its probative value, if any, is exceeded by the likelihood of confusion or misleading the jury. And Rules 702 and 703 have been relied on in countless cases to exclude proffered opinions that will not assist the trier of fact, or that lack a basis "reasonably relied upon by experts in the particular

[5] *Frye* seems to have contemplated instances in which scientists in a field may be divided on a pertinent question. But divisions among two respectable schools of scientists seldom are the issue in contemporary toxic-tort litigation.

field." Most of these decisions do not depend at all on *Frye*.[6] Indeed, the trial court in the present case relied on Federal Rules of Evidence 403 and 703. J.A. 229, 235.

No one heretofore has seriously thought that trial judges do not have the authorization and duty under the Federal Rules of Evidence to exclude scientific opinions that are not supportable in science. Yet that is where petitioners' argument leads. What is most disturbing about petitioners' position is that they do not stop by attacking the *Frye* formulation. They go further and reject, by distinguishing or by ignoring, each of the pertinent Federal Rules—leaving no function for the trial judge except essentially a ministerial one: to verify the expert's resumé, and then allow him or her to propound opinions at will.

Amicus submits that *Frye* offered a sound formulation, in no wise rejected in the Federal Rules, and that there is no basis on which to disapprove it. More importantly, however, this Court should recognize that, even without *Frye*, the Federal Rules of Evidence call for the exclusion by trial judges of opinions that ignore objective facts, or disregard the fundamental principles of the expert's discipline, or fail to follow a scientifically recognized methodology.

ARGUMENT

I. OPINION TESTIMONY BY EXPERTS THAT LACKS SCIENTIFIC SUPPORT REQUIRES JUDICIAL SCREENING.

A. Opinions, To Be Admissible, Must Meet Minimum Scientific Standards.

A starting point of evidence law is that the opinions of a witness generally are not admissible.[7] See Fed. R.

[6] "In practice . . . courts today all tend to admit the same evidence whether or not they purport to apply the *Frye* standard." Weinstein, *Improving Expert Testimony*, 20 U. RICH. L. REV. 473, 478 (1986).

[7] "It is no satisfaction for a witness to say that he 'thinketh' or 'persuadeth himself.'" *Adams* v. *Canon*, 1 Dyer 53bn., 73 Eng. Rep.

[Continued]

Evid. 701.[8] Neither are facts of which the witness lacks personal knowledge. Fed. R. Evid. 602. An exception is made for opinions of "experts." Fed. R. Evid. 702, 703. An "expert" witness is accorded a status and prerogatives not allowed to any other witness in a court of law. The expert, unlike a lay person, may give opinions;[9] answer hypothetical questions;[10] and rely on hearsay.[11] The court at the beginning of the testimony will consider and endorse the expert's qualifications, and in instructing the jury may specifically refer to him or her by the exalted title of expert.[12] But the expert's opinions must meet certain minimal specified standards.

The concept underlying the Federal Rules of Evidence is that the usual evidentiary prohibitions on conjecture, speculation and opinion will be relaxed *if* the opinion is more than just a personal belief or notion of the witness—if the witness in effect serves as a conduit through which the trier of fact is hearing the knowledge and experience of that learned discipline, as understood by persons reasonably following the principles and methodology of that discipline.[13]

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[7] [Continued]

117n., 118n. (St. Ch. 1622) (attributing to Chief Justice Coke). See also *Carter* v. *Boehm*, 3 Burr. 1905, 1918, 97 Eng. Rep. 1162, 1168 (K.B. 1766) (Mansfield, C.J.) ("It is mere opinion; which is not evidence").

[8] Rule 701 permits lay opinion testimony only when rationally based on personal observation and helpful to the trier of fact. *Cf. Queenan* v. *Oklahoma*, 190 U.S. 548, 549-50 (1903).

[9] Fed. R. Evid. 702. The expert need not disclose underlying facts or data unless required to do so. Fed. R. Evid. 705.

[10] *Barefoot* v. *Estelle*, 463 U.S. 880, 903 (1983).

[11] *E.g., United States* v. *Elkins*, 885 F.2d 775, 786 (11th Cir. 1989), *cert. denied*, 494 U.S. 1005 (1990).

[12] *E.g., Dawsey* v. *Olin Corp.*, 782 F.2d 1254, 1266 (5th Cir. 1986).

[13] "An opinion that purports to answer a scientific question without having engaged in an appropriate scientific inquiry is incapable of providing a systematic explanation that satisfies our demand for

The expert will be testifying to matters assumed to be beyond the ordinary understanding and experience of jurors. For that reason, the jurors do not possess their ordinary capability to test the testimony they hear against their own experience and common sense. See Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 HARV. L. REV. 40, 54-55 (1902). That is particularly true when the opinions concern unseen substances and unobservable processes. And "[b]ecause of its apparent objectivity, an opinion that claims a scientific basis is apt to carry undue weight with the trier of fact." *United States* v. *Baller*, 519 F.2d 463, 466 (4th Cir.), *cert. denied*, 423 U.S. 1019 (1975). There is greater danger of charlatanry.

The Federal Rules of Evidence establish a sort of bargain between the court and the expert: The court agrees to let the expert testify, and to bestow all the special privileges accorded an expert witness. In return, the witness assumes obligations as well. The most important of these is that the witness will not give lay opinions, but will testify as to what *science* knows on the subject. The witness will not go outside that body of science, and offer instead what are only his own particular speculation and hunches. A witness who seeks to do that is rejecting the terms by which expert testimony is permitted. In such a situation, the trial court has an obligation not to allow such opinions in evidence. The expert's opinions need to have a basis that would be recognized as scientific by others who profess that discipline. "[I]f an expert opinion is so fundamentally unsupported that it can offer no assistance to the jury, then the testimony should not be admitted." *Loudermill* v. *Dow Chem. Co.*, 863 F.2d 566, 570 (8th Cir. 1988).

For an expert opinion to have reliability and be helpful to the factfinder, there needs to be: (1) a basis in fact, not speculation; (2) a theory founded in science; (3) a

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rational proof." Brief of the Carnegie Commission on Science, Technology and Government as *Amicus Curiae* at 7.

methodology founded in science.[14] Therefore the Federal Rules assign the judge a screening role. Questions concerning the qualification of a witness or the admissibility of evidence "shall be determined by the court." Fed. R. Evid. 104(a). An opinion should not be admissible if "the plaintiff's expert brought to court little more than his credentials and a subjective opinion." *Viterbo* v. *Dow Chem. Co.*, 826 F.2d 420, 421 (5th Cir. 1987).

B. Evidence Must Be Based on Present Knowledge.

The fundamental issue that this case concerns is whether liability decisions of the district courts—decisions of whether a party is at fault and must pay damages—are to be based on unscientific opinion and speculation. To exclude non-science opinions from court is not, as some *amici* warn, "dangerous" or "inimical to the search for truth."[15] The search for truth requires that scientific issues be debated in the many appropriate scientific fora—seminar rooms, peer-reviewed journals, laboratories and conferences. The development of scientific knowledge is if anything furthered, and certainly not inhibited, by refusing to make courtrooms available for the exposition in liability suits of conclusions not based on scientific principles and methodology.

Petitioners need to answer this question: If the scientific community—which has only academic and professional inquiry at stake—does not recognize an individual's assumptions or methodology as within that discipline, then why should the judiciary—which is concerned instead with the task of determining facts and causation as understood at the time of trial, so as to decide whether to

[14] Thus another *amicus* has suggested as a measure of admissibility, "has plaintiff's expert's claim been empirically tested or is it merely a hunch?" Brief of the Carnegie Commission, *supra*, at 21. "[C]ourts should focus on determining whether the expert engaged in recognized forms of scientific practice in reaching his or her conclusion." *Id.* at 5.

[15] Brief *Amici Curiae* of Physicians, Scientists, *et al.* at 14, 15, 16.

impose liability—be required to accept the same opinions as evidence in what ought to be an even more exacting arena? It would make no sense for the judicial system to become more gullible than the scientific community.[16]

It is one thing to point out that scientific knowledge sometimes proceeds irregularly, and to observe that even the majority of scientists may later turn out in retrospect to have been wrong about something. (The majority of scientists often are right in their conclusions, too.) It would be perverse for a court to order a party to pay damages based on the assumption that ordinary science is wrong, and that the correct answer will be found through a method that is not consistent with science at all.[17] What science may learn in the future, only the future knows. To decide cases, courts have no rational choice but to look at scientific knowledge as it exists now. And no legal system for compensating persons with injuries truly caused by chemicals can function in the long run if it cannot distinguish valid and provable claims from those that are based on nothing but conjecture.[18]

[16] "Professor Bryan would not accept from his students or those who submit papers to his journal an essay containing neither facts nor reasons; why should a court rely on the sort of exposition the scholar would not tolerate in his professional life?" *Mid-State Fertilizer Co.* v. *Exchange Nat'l Bank*, 877 F.2d 1333, 1339 (7th Cir. 1989). See also *In re Air Crash Disaster*, 795 F.2d 1230, 1234 (5th Cir. 1986) ("opinions that they might not be willing to express in an article submitted to a refereed journal").

[17] Contrary to the suggestion of one group of *amici*, see Brief of American Society of Law, Medicine and Ethics, *et al.* at 10-24, the policymaking standards of regulatory agencies in risk assessment are certainly not the touchstone for judicial determinations of causation and liability. Regulatory agencies are concerned with a different issue, risk. "A clear distinction currently exists between a standard of proof used in regulation and a standard used in determining tort liability." Black & Lilienfield, *Epidemiologic Proof in Toxic Tort Litigation*, 52 FORDHAM L. REV. 732, 777 (1984).

[18] It should not be assumed that all plaintiffs are on one side of this issue and all defendants on the other. Sometimes legitimate claims for damages are based on scientific proof. Where science supports a plaintiff's case, a defendant should not be permitted to

Excluding scientifically unsupported opinions from the courtroom determination of facts does not choke off new learning. The opinion testimony screened out by the district courts under the Federal Rules of Evidence is not news of discoveries from scientific pioneers who tear themselves away from their clinics and laboratories to spend a few minutes at the courthouse sharing their learning. Nearly always it is something quite different: the statements of what one observer referred to as the "demimonde of professional witnesses who devote the bulk of their time to litigation." [19]

C. Without Judicial Screening, Abuse Is Inevitable.

The efflorescence of non-science scientific opinions is not simply a lament of defendants. The courts have pointed it out: "ukase in the guise of expertise is a plague in contemporary litigation." *Mid-State Fertilizer Co.* v. *Exchange Nat'l Bank*, 877 F.2d 1333, 1340 (7th

use pseudo-science to avoid liability. And the legitimate plaintiffs have a strong interest in not having their cases buried in an avalanche of spurious claims, and in not having serious science supporting their contentions tainted by association with unsupportable methodologies.

[19] Endicott, *Quack Medicine and Tort Litigation: The Scientific Method or 'Methodology?'*, 7 TOXICS L. REP. 288, 292 (1992) (footnote omitted). *Cf., e.g.*, 28 TRIAL 101-13 (Dec. 1992) (advertisements by expert witnesses). Medical opinions in "toxic tort" cases often come not from treating physicians, but rather from doctors who see patients (if they see them at all) only on referral from attorneys. *E.g.*, a medical doctor whose opinions were offered in the *Paoli* case, discussed *infra* pp. 21-29:

> Q. Do you have any patients that you see on a regular basis who are not involved in litigation?
>
> A. No. . . .
>
> Q. And those examinations were conducted—we've heard a lot of testimony about, in a law office?
>
> A. That's clearly established, yes.

Deposition of Janette D. Sherman, M.D., in *Paoli*, *supra* n. 2, Nos. 86-2229 (E.D. Pa.) (hereinafter "P.D.") at 26; transcript of hearing in *Paoli* (E.D. Pa. July 29, 30, 1992) (hereinafter "P.T.") at 143.

Cir. 1989). The effects are so national in scope that federal officials have worried that

> it has become all too common for "experts" or "studies" on the fringes of or even well beyond the outer parameters of mainstream scientific or medical views to be presented to juries as valid evidence from which conclusions can be drawn.

REPORT OF THE TORT POLICY WORKING GROUP 35 (1986). Dozens of commentators have expressed similar dismay. *E.g.*, Imwinkelried, *Science Takes the Stand: The Growing Misuse of Expert Testimony*, 26 THE SCIENCES 20 (Nov.-Dec. 1986); Weinstein, *Improving Expert Testimony*, 20 U. RICH. L. REV. 473 (1986).

The unfortunate fact—but it is a fact—is that a certain number of degree-holding individuals have demonstrated themselves willing, while wearing the mantle of their professional degrees, to swear for pay to propositions that are simply not supported in science at all. It is not necessary to assume that none of them is sincere, or that all are venal. The simple reality is that "[a]n expert can be found to testify to the truth of almost any factual theory, no matter how frivolous . . . ." Weinstein, *supra*, 20 U. RICH. L. REV. at 482. "It is quite apparent that experts are readily available to present essentially frivolous theories . . . ." Berger, *A Relevancy Approach to Novel Scientific Evidence*, 115 F.R.D. 89, 91 (1987). As the Solicitor General last year pointed out:

> Gone are the days in which "codes of silence" made it difficult to find an expert witness willing to testify in certain fields. Today, attorneys can pick from a host of readily available expert witnesses, some of whom regularly purchase glossy advertisements in legal magazines. Such practices have seriously impaired the utility of expert testimony as an aid to the jury. At their extreme, they have led to an influx of "junk science" into the courtroom, peddled by those who are prepared to flaunt the arcanum of a particular expertise as a means of deceiving the trier

of fact. Judge Weinstein has noted that such testimony "validat[es] the case sufficiently to avoid summary judgment and forc[e] the matter to trial. At the trial itself, an expert's testimony can be used to obfuscate what would otherwise be a simple case."

The purveyors of "junk science" tend to be limited only by their own creativity. They range from those testifying that car accidents cause cancer, to those arguing that minute quantities of hazardous substances can cause a type of "chemical AIDS" responsible for virtually any type of ailment. The only things these "experts" have in common are that their theories have been emphatically rejected by reputable authorities as unfounded, and that they impose enormous costs both on litigants and society as a whole.[20]

II. THE FEDERAL RULES OF EVIDENCE ALLOW AND REQUIRE TRIAL COURTS TO CONTROL ABUSES OF OPINION TESTIMONY BY EXPERTS.

Trial judges, as the volume of litigation involving experts has ballooned, have exercised their responsibility to exclude opinions that are not recognizable science. The control they have been exercising has not depended just on *Frye*. It is firmly grounded, and was fully intended, in the Federal Rules of Evidence. Courts never have seriously questioned that the Federal Rules of Evidence generally (Rules 104(a), 401, 402, 602 and 701) and specifically (Rules 403, 702 and 703) contemplate that trial judges should exclude expert opinions that do not meet minimal criteria of scientific reasoning and methodology. *Cf. United States* v. *Abel*, 469 U.S. 45, 50 (1984) (Rules intend cross-examination for bias). As applied to experts, the purpose of the rules is consistent, and their provisions even sometimes redundant. Some courts have relied more often on one rule, some courts on another.

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[20] Starr, *Overview*, in PRESIDENT'S COUNCIL ON COMPETITIVENESS, A PLAN TO IMPROVE AMERICA'S SYSTEM OF CIVIL JUSTICE 13 (1992), quoting in part Weinstein, *Role of Expert Testimony and Novel Scientific Evidence in Proof of Causation* 12 (address to ABA Annual Meeting 1987).

A. Rule 104(a).

Rule 104(a) confirms the traditional function of the trial judge to rule on "[p]reliminary questions concerning . . . the admissibility of evidence." See also Fed. R. Evid. 1101(d)(1). In deciding such questions of admissibility, trial judges have always been allowed a wide discretion. "Whatever may be the general formulation, the essential requirement is that [mere speculation be not allowed to do duty for probative facts . . . ." *Galloway* v. *United States*, 319 U.S. 372, 395 (1943). The trial judge's role as applied to experts was stated by this Court in *Salem* v. *United States Lines Co.*, 370 U.S. 31, 35 (1962):

> the trial judge has broad discretion in the matter of the admission or exclusion of expert evidence, and his action is to be sustained unless manifestly erroneous.

Nothing in the Federal Rules of Evidence so much as hints at a contraction of this "broad discretion," or alters in any respect the "manifestly erroneous" standard of review.[21]

B. Rules 401 and 402.

Rule 401—never cited by petitioners at all—provides that "relevant evidence" is "evidence having any tendency to make the existence of any fact that is of consequence

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[21] See also, *e.g.*, *Spring Co.* v. *Edgar*, 99 U.S. 645, 658 (1879) ("very much a matter of discretion with the court whether to receive or exclude the evidence"); *Winans* v. *New York & E.R.R.*, 21 How. 88, 101 (1859) (judge "cannot be compelled to receive their opinions as matter of evidence"); *In re "Agent Orange" Product Liability Litigation*, 611 F. Supp. 1223, 1239 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied sub nom. Lombardi* v. *Dow Chem. Co.*, 487 U.S. 1234 (1988); *cf. Bourjaily* v. *United States*, 483 U.S. 171, 177-79 (1987). Nothing in *Barefoot* v. *Estelle*, *supra*, holds otherwise; on the contrary, this Court there affirmed trial court rulings on admission of expert testimony, refusing to adopt a *per se* rule excluding "psychiatrists, individually and as a class." 463 U.S. at 885. The Court of Appeals here upheld the trial court's determination even applying (inconsistently with *Salem*) a *de novo* standard. J.A. 238.

to the determination of the action more probable or less probable than it would be without the evidence." That surely does not include opinions not grounded in science. Petitioners seem to assume that unsupportable opinions of people owning scientific credentials are relevant within the meaning of Rule 401. See Pet. Br. 19, 25. But generally a witness' opinion, unless it can qualify as expert testimony, is *not* relevant—no more than that of any lay person in the courtroom. "It is of course not necessary for the jury to accept the expert's opinion, but were it not really of possible weight with them, it would not be relevant . . ." Hand, *supra*, 15 HARV. L. REV. at 52.[22] By assuming the testimony is relevant, petitioners beg the question. Rule 402 unambigously declares that "Evidence which is not relevant is not admissible." Rules 401 and 402 alone, without more, would authorize a district court to exclude on relevancy grounds opinions which do not meet certain minimum standards as scientific expert testimony.

C. Rule 403.

Rule 403, which the District Court cited as one authority for its ruling in the present case, J.A. 229, in unambiguous language plainly authorizes the exclusion of prejudicial baseless opinion testimony:

> evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury . . . .

It certainly applies to expert opinions, even without *Frye*. *United States* v. *Jakobetz*, 955 F.2d 786, 794 (2d Cir.), *cert. denied*, 113 S. Ct. 104 (1992). "Fed.R.Evid. 403

[22] See also *Christophersen* v. *Allied-Signal Corp.*, 939 F.2d 1106, 1114 (5th Cir. 1991) (*en banc*) ("[e]ven if Rule 703 will not require the exclusion of such an unfounded opinion, general principles of relevance will"), *cert. denied*, 112 S. Ct. 1280 (1992); Berger, *supra*, 115 F.R.D. at 89; 3 J. WEINSTEIN & M. BERGER, WEINSTEIN'S EVIDENCE ¶ 702[02] at 702-18 (1992) (Rule 702's "helpfulness test subsumes a relevancy analysis"); *cf. Huddleston* v. *United States*, 485 U.S. 681, 689 (1988).

provides an independent means for excluding expert testimony." *Hines* v. *Consolidated Rail Corp.*, 926 F.2d 262, 274 (3d Cir. 1991).

The "probative value" of non-science opinions from scientists is nil. The danger they hold for "unfair prejudice," "confusion," and "misleading" is practically infinite. See *Christophersen* v. *Allied-Signal Corp.*, 939 F.2d 1106, 1120-22 (5th Cir. 1991) (Clark, C.J., concurring), *cert. denied*, 112 S. Ct. 1280 (1992). Courts frequently and appropriately rely on Rule 403 to exclude unsupported expert testimony, just as the District Court did here.

D. Rules 701, 702 and 703.

Petitioners' brief ignores Rule 701, and asks this Court to reinterpret Rules 702 and 703 so as to leave them toothless, and to erase years of decisions in the courts of appeals that have applied both rules to screen out non-science opinions.

Rule 701 generally prohibits lay opinion testimony. As the Advisory Committee noted, it contemplated that "[i]f . . . attempts are made to introduce meaningless assertions which amount to little more than choosing up sides, exclusion for lack of helpfulness is called for by the rule." Committee on Rules of Practice and Procedure, Judicial Conference, *Rules of Evidence for the United States Courts and Magistrates*, 51 F.R.D. 315, 402-03 (1971).

Rule 702 provides a limited exception for opinions of experts, provided what they offer is "scientific, technical, or other specialized knowledge" that "will assist the trier of fact." Repeatedly the federal courts have applied this rule to ensure that expert opinions be in fact "scientific"—based on a reliable methodology grounded in the relevant scientific or specialized discipline. *E.g.*, *Loudermill* v. *Dow Chem. Co.*, *supra*, 863 F.2d at 569-70. Circuits that do not follow the *Frye* formulation recognize without hesita-

tion that Rule 702 requires trial judges to screen the scientific validity of the method invoked as the basis for the expert's conclusions. *E.g.*, *DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 954 (3d Cir. 1990) ("Rule 702's helpfulness requirement implicitly contains the proposition that expert testimony that is based on unreliable methodology is unhelpful and therefore excludable"); *In re Paoli R.R. Yard PCB Litigation*, *supra* n.3, 916 F.2d at 856-57 ("the court must analyze the reliability of that methodology under . . . Rule 702 . . ."); see also *Christophersen* v. *Allied-Signal Corp.*, 939 F.2d 1106, 1114 (5th Cir. 1991) (*en banc*) ("[d]istrict judges may reject opinions founded on critical facts that are plainly untrustworthy, principally because such an opinion cannot be helpful to the jury"), *cert. denied*, 112 S. Ct. 1280 (1992).

Rule 703 similarly requires that "[t]he facts or data in the particular case upon which an expert bases an opinion or inference . . . . [be] of a type reasonably relied upon by experts in the particular field." Otherwise, the general prohibition of Rule 602 applies: that a witness may not testify to matters without personal knowledge. The trial court "must therefore look behind [the] ultimate conclusion . . . and analyze the adequacy of its foundation." *Richardson* v. *Richardson-Merrell, Inc.*, 857 F.2d 823, 829 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989); see also *Lynch* v. *Merrell-National Labs.*, 830 F.2d 1190, 1196-97 (1st Cir. 1987) ("the district court's firm rejection here of foundationless expert testimony was necessary, admirable, and entirely within the discretion of the court under Federal Rules of Evidence 403 and 703"); *Lima* v. *United States*, 708 F.2d 502, 507 (10th Cir. 1983) (expert's opinion "did not reach the threshold standards for admissibility as set forth under Fed. R. Evid. 703"); *Coal Resources, Inc.* v. *Gulf & Western Industries, Inc.*, 865 F.2d 761, 772 n.4 (6th Cir. 1989) ("the requirement [of Rule 703] that an expert ground his opinion on reliable data rather than pure speculation"). Again, even the non-*Frye* circuits often use Rule 703

to reject opinions lacking a foundation in facts. *E.g.*, *Pennsylvania Dental Ass'n* v. *Medical Service Ass'n*, 745 F.2d 248, 262 (3d Cir. 1984), *cert. denied*, 471 U.S. 1016 (1985).

If all these courts for all these years have been so wrong about the meaning of the Federal Rules, it is awfully late to discover that. With rules and statutes, when a sensible understanding has been well established, the appropriate way to change it, if at all, is by a revised enactment, not by reinterpretation. *Cf.*, *e.g.*, *Monessen S.W. Ry.* v. *Morgan*, 486 U.S. 330, 338 (1988); *Square D Co*, v. *Niagara Frontier Tariff Bureau, Inc.*, 476 U.S. 409, 424 (1986); *Illinois Brick Co* v. *Illinois*, 431 U.S. 720, 736 (1977); *Flood* v. *Kuhn*, 407 U.S. 258, 283-84 (1972).

III. PETITIONERS PROPOSE A RADICAL CHANGE, WHICH SHOULD BE REJECTED.

Although petitioners' brief adopts a moderate tone, its modesty is Swiftian.[23] To accept its reasoning would compel a stark change in the functioning of federal trial judges. Instead of screening out opinions that are shown not to be scientifically based at all, the role of judges under petitioners' plan would become ministerial, reading resumés and then allowing testimony.

Petitioners came to this Court attacking the formula of *Frye* v. *United States*, 293 Fed. 1013 (D.C. Cir. 1923). Now that they are here, they go on to challenge the law applied in all the Circuits. They travel one by one through the Federal Rules of Evidence, arguing that none of the Rules authorizes trial courts to perform a meaningful screening function for expert opinion testimony, other than to inspect credentials.[24] Petitioners'

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[23] *Cf.* J. SWIFT, A MODEST PROPOSAL (1729).

[24] See, *e.g.*, Brief for Petitioners at 32 ("Rule 702 authorizes only a generic inquiry whether 'specialized knowledge will assist the trier of fact,' and a further inquiry whether the particular witness is 'qualified' . . . ."); *id.* at 35 ("Rule 703 provides no textual support

argument would destroy not just *Frye* but all screening by district judges of proffered opinion testimony from experts. They would leave the question whether the opinions of a purported expert are science as one more issue for the jury to decide. That has never been the law.[25]

Nor should petitioners' concept become the law. Under such a regime, each and every jury in a case involving technical issues could be required to reinvent the scientific method of inquiry, delving into fundamental issues about scientific proof, including the logic of replicable experiment and the nature of statistical inference. Every trial could turn into an academic seminar. No form of analysis could be excluded as long as some witness possessing a credential could be found to support it, no matter how many times other juries, judges, or scientists had concluded that such analysis was not reliable. A court could not exclude expert opinions based on polygraph tests, for example, or on hypnosis or narcoanalysis, and the reliability of each of these methods would have to be reargued *ab initio* in every case.

Even if every single jury reached the correct decision in the end, the burdens on the judicial system, on liti-

---

for placing special limitations on expert testimony"); *id.* at 39 n.68 (Rule 403, although applicable, is an "unlikely basis for exclusion").

[25] "The jury was not absolute master of fact in 1791. Then as now courts excluded evidence for irrelevancy and relevant proof for other reasons." *Galloway* v. *United States*, *supra*, 319 U.S. at 390. That the judge rules on questions of admissibility of evidence is one of the most ancient defining characteristics of the common-law jury system, and certainly part of the right that was "preserved" by the Seventh Amendment. Whether an expert offered "qualifications and knowledge" that could offer reliable help in a particular case was always "a preliminary question for the judge presiding at trial." *Stillwell & Bierce Mfg. Co.* v. *Phelps*, 130 U.S. 520, 527 (1889); see also *Spring Co.* v. *Edgar*, *supra*; Fed. R. Evid. 104(a). As this Court observed with respect to the judge's role in summary judgment under Fed. R. Civ. P. 56, the jury system includes "due regard . . . also for the rights of persons opposing such claims and defenses to demonstrate . . . prior to trial, that the claims and defenses have no factual basis." *Celotex Corp.* v. *Catrett*, 477 U.S. 317, 327 (1986).

gants, and on society of such an approach would be staggering, and absolutely unnecessary. Furthermore, of course, given the inherent uncertainties of litigation, some erroneous decisions would occur. The guarantee of trial by jury gives a litigant the right to have a jury assess the particular facts involved in the case before it. The guarantee does not create a right to have each jury devise its own new and unique definition of scientific reality.

Petitioners nevertheless seek to dispose of the Federal Rules of Evidence by ignoring some and radically redefining others. Petitioners assume, first, that any opinions delivered by an expert—no matter how lacking in scientific methodology—are relevant under Rule 401 and therefore admissible under Rule 402. They argue that none can be excluded under Rule 702, because they say it deals only with qualifications and whether expert testimony generically would be helpful. Rule 703 has no place, they say, because they read it as simply a hearsay exception allowing experts to look at certain facts outside the record. Rule 403 gives them a great deal of trouble, because even petitioners cannot deny that its terms squarely apply. So they scarcely mention it, shrugging that it would be an "unlikely" vehicle, seldom overcoming the "presumption of admissibility" for expert opinions that petitioners discern in the Federal Rules as a whole. Pet. Br. at 37, 38 n.68.

Petitioners bear an extraordinary burden when they suggest that for the past nearly two decades courts in every circuit have been mistaken in excluding unsupported expert opinions under Rules 702 and 703 as well as Rule 403—just as those courts had done prior to the adoption of the Federal Rules. If the drafters of the Rules, and this Court and the Congress in adopting them, had intended to strip trial judges of their customary and essential role, it is remarkable that nothing in the history of the Rules mentions such a thing.

Yet petitioners ask this Court not just to do away with *Frye*, but also to hold that under the Federal Rules

of Evidence district judges have virtually no choice but to allow into evidence any opinion by a person whose credentials satisfy the undemanding standard of Rule 702.[26] It is their attack on the trial judge's usual role under the Federal Rules that makes this Court's decision in this case so important.

IV. "TOXIC TORT" CLAIMS PARTICULARLY REQUIRE JUDICIAL SCREENING OF OPINION TESTIMONY.

Human illnesses have always been a part of human life. Only in the past few decades, however, have chemical products come to play a large role in manufacturing and health care, and only in very recent years has technology made it possible to measure in incredibly minute quantities—one part per billion or less—the presence of a particular substance in human tissue or the environment.

The result has been "toxic tort" litigation: a new kind of tort suit in which individuals claim that exposure to an often infinitesimal quantity of a substance is responsible for an illness or physical condition. Such claims cannot be proved by evidence that is part of common experience, like two automobiles colliding. Instead, the claims nearly always ask juries to determine liability based entirely on testimony of experts as to what science knows about things that cannot be seen, felt, or experienced. Typically, besides injury (which may lack any observable symptoms), it is necessary to prove significant exposure to the substance; that the substance is capable of causing the illness or injury; and that in fact it did so in the particular case. Often all depend on expert testimony.

Given the wide dispersal and use of chemical products of all kinds, "toxic torts" are very easy to allege. If reliable science does not support the claims, however, no tort has occurred. That has not stopped dubious claims

[26] A person may qualify as an "expert" under Rule 702 by virtue of "knowledge, skill, experience, training, or education."

from being brought.[27] A judge who is also a distinguished commentator on the Federal Rules has cautioned that

> careful scrutiny of proposed expert evidence is especially appropriate in the toxic tort area. The uncertainty of the evidence in such cases, dependent as it is upon speculative scientific hypotheses and epidemiological studies, creates a special need for robust screening of experts and gatekeeping under Rules 403 and 703 by the court.

In re "Agent Orange" Product Liability Litigation, *supra* n. 21, 611 F. Supp. at 1260 (Weinstein, C.J.).

The reality of what expert testimony could become, unless trial courts continue to exercise their screening role, is apparent in a group of toxic-tort claims that are currently in court, *In re Paoli R.R. Yard PCB Litigation*, *supra* n. 2. In these cases a number of plaintiffs who resided near the Paoli, Pennsylvania railroad yard claimed that forty-seven different kinds of illnesses[28] had been caused by alleged exposure to PCBs (polychlorinated biphenyls)[29] that had spilled on soil at the railroad yard. One group of experts proffered by the plaintiffs was cross-examined in depositions, and then their opinions were excluded by the trial judge. After the court of appeals remanded and suggested that *in limine* evidentiary hearings be held, the plaintiffs presented a new set of experts,

[27] Plaintiffs in such cases of course are not necessarily insincere. To seek an external agent to blame for an ailment "is human nature." *In re "Agent Orange" Product Liability Litigation*, 818 F.2d 145, 149 (2d Cir. 1987), *cert. denied sub nom. Pinkney* v. *Dow Chem. Co.*, 484 U.S. 1004 (1988).

[28] These included asthma, insomnia, anemia, anorexia, swollen hands, seizures, enlarged prostate, Parkinson's disease, cardiovascular disease, arthritis, gastritis, lung disease, brain cancer, hypertension, impotency, jaundice, pancreatic cancer, muscle cramps, irritability, and stiff joints.

[29] PCBs became common in many industrial processes and products beginning about 1930, and were used for decades in railroad electrical transformers to prevent fires on freight and passenger trains.

whose depositions were taken. The trial judge then held five days of pretrial evidentiary hearings and a day of argument, at significant expenditure of judicial and other time and resources, after which he excluded the second set of opinions under Federal Rules of Evidence 403, 702 or 703.[30] The opinions of these *Paoli* experts vividly illustrate lack of the essential prerequisites: (1) a basis in fact rather than speculation; (2) a theory based on principles followed in the discipline; (3) a scientifically recognized methodology.

A. Lack of Factual Basis.

1. A chemist offered his opinion that the Paoli residents must have high levels of PCBs in their bodies as a result of airborne transmission, simply because high levels of PCBs had been found in the soil. By a formula of his own devising, used by no one else, he sought to infer from two soil samples the air levels of PCBs, from which he inferred high levels in the plaintiffs. He ignored actual air samples which existed—and which contradicted the results of his theory. He also ignored the actual measured body samples of the plaintiffs' PCB levels—which also contradicted his numbers.[31]

2. A self-styled "immunologist" (who had completed only one graduate-level course that included immunology, but owned a firm providing litigation-support services) concluded "[w]ithin a reasonable degree of scientific ceratinty" that because of PCB exposure, the plaintiffs must have developed altered immune systems and therefore were predisposed to many diseases. He conceded that he presented this opinion without knowing the actual PCB body levels of any plaintiff, and simply "assumed" these to be high. He acknowledged that his conclusions

[30] See n. 2, *supra*; 916 F.2d at 836, 854-55, 858, 859. The rulings excluding the second set of opinions are currently challenged on appeal.

[31] *Paoli* appendix in U.S. Court of Appeals, Third Circuit, Nos. 88-1973 etc. (hereinafter "P.A.") at 4224-28, 9256-57 (Herbert Allen, Ph.D.).

that such alleged injury had occurred could be verified only by a series of tests that he had not performed.[32]

3. A physician opined, without knowing any plaintiff's level of exposure, that PCBs had been causes of the various illnesses alleged,[33] although it is "the most fundamental and pervasive concept in toxicology" that dose level must be known to determine whether a substance can cause a reaction.[34] The district court found as to this physician, whose office was a post office box, that "Since 1976, substantially all of the income that she generated from her professional activities has come from work in cases that were involved in litigation. . . . She has been involved in over 8,000 cases since 1976, and has given over 800 depositions . . . ." 1992 WL 323493 at *2. The doctor testified:

> Q. . . . Now, Doctor, I believe that you testified that throughout your practice, you have, from time to time, examined people whom you believe to have been exposed to PCBs, is that correct?
>
> A. That's correct.
>
> Q. And is it fair to say that you can't remember a single case in which you've examined such a person, where you reached—where you reached a conclusion that PCBs did not cause any adverse health effects, is that correct?
>
> A. Well, that's probably true.[35]

4. The same physician repeatedly offered medical diagnoses without examining patients. For example:

> Q. Now, did you make a determination that exposure to transformer fluid caused Patricia Ingram to suffer from asthma?
>
> A. In part.

[32] P.A. 3354, 5987, 6022, 6054-55, 6120, 6133 (Arthur C. Zahalsky, Ph.D.).

[33] CASARETT & DOULL'S TOXICOLOGY 18 (M. Amdur *et al.* 4th ed. 1991).

[34] P.D. at 66-67 (Janette D. Sherman, M.D.).

[35] P.T. 140.

Q. Okay. And you didn't examine Patricia Ingram, did you?

A. No.[36]

5. Another expert, who was a physicist and mechanical engineer holding a Ph.D. and referred to himself as a "professional environmental scientist," concluded that the plaintiffs had been exposed to PCBs at unusually high levels. However, he could not provide any factual data to support what he called his "scientific conclusion." [37]

B. Lack of Scientific Theory.

The opinions of experts that trial judges exclude often are characterized by absence of any articulable supporting scientific theory, or by assertions of having suddenly discovered a truth unknown to all others:

1. The "immunologist" previously referred to explained his scientific reasoning to be that if the plaintiffs were sick, it was because of PCBs:

Q. So you're saying that because these people have the conditions they have, you think that's enough

---

[36] P.T. 153. The same physician was asked as to ten plaintiffs whose afflictions she attributed "to a reasonable degree of medical certainty" to PCBs:

Q. Did you examine those ten people?

A. I examined three of the ten.

Q. But you did not examine the others?

A. I did not examine the other seven, that's correct. . . .

Q. Did you request that those tests be done on these plaintiffs before rendering your opinion?

A. No.

P.D. 30-33; P.T. 166.

[37] Q. Do you have any information, sir, as to the amount of PCBs in use at the rail yard at any time?

A. I don't know. . . .

Q. Do you have any information about the levels of PCBs that were in the run-off?

A. I know of no measurements, no. . . .

Q. Have you made any effort to quantify the intake of PCBs that you believe any plaintiff experienced in this case?

A. No, I don't believe that can be done.

P.A. 8744, P.T. 85-86, 120-22 (Ian C. T. Nisbet, Ph.D.).

to show that they got them from being exposed to PCBs, is that right?

A. Yes, I do.

Q. Just because they have the conditions?

A. Because they have these conditions, yes.[38]

When it was pointed out that an article he had cited as authority concerned another chemical, not PCBs, he replied, "it doesn't matter to me." [39] Other physicians and scientists stated that "[t]here is no evidence to support the theory that PCBs suppress immune functions in humans;" that the expert's opinions "are mere conjecture;" that his methodology "is scientifically inadmissible;" and that "[n]o doctor would rely on the tests described in [the expert's] affidavit for any purpose whatsoever." [40]

2. A toxicologist, who said that "I have been involved in a lot of medical causation cases," claimed to have devised after being retained for the case a unique "fingerprinting" method, not known to anyone else, by which she could look at chromatograms and decide, without measuring or using instrumentation, whether molecules of PCBs in a plaintiff's blood had originated at the Paoli Railroad Yard. (She concluded in each case that they had.) She acknowledged that "I can't think of anybody" who had claimed in any published report that such a process was possible. With the exception of one page of handwritten notes, she had no work papers or written report indicating what procedures she had followed, her

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[38] P.A. 6275 (Arthur C. Zahalsky, Ph.D.).

[39] P.A. 6115. Nor could he cite other studies:

Q. Well, what studies are you aware of which would enable you to compare the experiences of the people living adjacent to the railyard to other people?

A. The studies that I have read throughout the years.

Q. Can you name one or two of them?

A. Not even one.

Q. Why not even one?

A. Because I don't recall them. I don't remember these studies. (P.A. 6267.)

[40] P.A. 3814, 4252, 9942, 9944.

conclusions, or the basis for her conclusions. A professor of toxicology and pharmacology who examined her submission stated that the equipment used could not support such an analysis, and that because of the absence of controls and the inability to reproduce her experiment, "[h]er analysis thus lacks any semblance of scientific validity." [41]

3. Published authorities whom experts invoke sometimes are only press clippings, as when a *Paoli* expert cited a supposed author who turned out to be the name of a newspaper.[42] Another expert physician offered by the plaintiffs relied principally on newspaper reports.[43]

C. Lack of Scientific Methodology.

It is an axiom of medicine (as well as of logic) that diagnosis requires elimination of likely other causes before a particular cause can be assigned—what physicians refer to as "differential diagnosis." In particular, known common causes of a disease must be eliminated before it

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[41] P.A. 3328-29, 4191-95, 4954, 5031-32, 5063-67, 5220-21, 5244-45, 5328, 5331-34, 5336-38 (Deborah Barsotti, Ph.D.).

[42] Q. You identified a study by Battleboro or a reference by Battleboro as supporting your contention that PCBs were found to be associated with asthma. Do you have that study with you today?

A. I'm glad you asked me. Yes, I brought in Battleboro, I beg your pardon. It refers to the B[r]attleboro press. . . . It was not an author, and that was my mistake . . . .

Q. . . . [Y]ou were referring at some point to what you called the Battleboro article, and you produced a two-page article which appears to be a newspaper article . . . . And [the subject of the article] is quoted as saying: Quote, we lost because we can't prove that the oil in the well made us sick, close quote. Is that correct? . . .

A. That's what it says, yes.

P.D. 995-99; see also *id.* 375-76, 439-40.

[43] P.A. 6471-72, 6389, 6411, 6416, 6471-72, 6491 (Harry Shubin, M.D.).

is attributed to something else." [44] That essential component of medical methodology disappeared from the opinions offered by physicians in *Paoli*:

1. One physician offered by the plaintiffs was willing, based on a plaintiff's assertion of insomnia and irritability, to testify "to a reasonable degree of medical certainty" (although he did not examine either the individual or even his medical records) that the alleged conditions were caused by PCB exposure "until otherwise proven":

> Q. Regardless of any of the number of other factors or possible causes?
>
> A. That's correct.[45]

2. Another physician acknowledged, sometimes impatiently, that all the diagnoses offered failed to eliminate likely known causes. For high blood pressure:

> Q. . . . Did you consider any alternative causes other than PCB exposure in determining what caused his elevated blood pressure?
>
> A. Not specifically. I wouldn't rule them out, but I have not looked at any others specifically.
>
> Q. Did you look at any generally?
>
> A. No.

For stomach cancer:

> Q. Well, you said that PCBs was a significant contributing factor [to the plaintiff's stomach cancer]. Are there others that you believe may have played a role?
>
> A. There may have been. I don't know.

For asthma:

> Q. Is is your opinion, Doctor, that her asthma was caused by exposure to transformer fluid?
>
> A. I think it is a factor, yes. . . .

---

[44] See, *e.g.*, P. CUTLER, PROBLEM SOLVING IN CLINICAL MEDICINE 154-56 (2d ed. 1985); R. JUDGE, *et al.*, CLINICAL DIAGNOSIS 511 (4th ed. 1982); M. DELP, *et al.*, MAJOR'S PHYSICAL DIAGNOSIS 42 (9th ed. 1981); see also *In re "Agent Orange" Product Liability Litigation, supra* n.21, 611 F. Supp. at 1250-54.

[45] P.A. 7124, 7169-71 (G. John DiGregorio, M.D., Ph.D.).

Q. Have you ruled out any causes of asthma other than exposure to transformer fluid in the case of Patricia Ingram?

A. No.

Q. You have not done that?

A. That's what I just said.

For episcleritis:

Q. What causes did you rule out?

A. I believe it was his exposure to the dielectric fluids, which included PCBs that caused his multiple problems, including his episcleritis.

Q. I know that, Doctor. What I'm asking you is what alternative causes did you consider and rule out as potential causes of his episcleritis, other than exposure to PCBs?

A. I can't think of any.

For anemia:

Q. Did you rule out the other known causes of anemia in Mr. Cunningham's case?

A. No.[46]

3. Another physician, who described himself in his resumé as "Medical Advisor" to the "Federal Judiciary," examined three plaintiffs and said that they suffered from multiple illnesses caused by PCBs, even though none of their treating physicians had so concluded. He also stated that PCBs had caused the death of a man he had never seen, whose medical records he had never examined, and the circumstances of whose death were unknown to him. He also concluded that PCBs had caused severe illnesses in a plaintiff whose blood test showed no PCBs at all. He explained that his scientific method was simply to attribute all adverse medical conditions to PCBs "until I would be shown that I was wrong."[47]

4. The toxicologist previously referred to also offered opinions "to a reasonable scientific certainty" that each

[46] P.D. 206, 388-89, 437-38, 679, 917.

[47] P.A. 3278, 3282-91, 3296, 6394, 6438-40, 6723 (Harry Shubin, M.D.).

plaintiff who retained her (none of whom she had ever met) had illnesses caused by PCBs, based solely upon medical records and an information form supplied by their counsel. Other scientists concluded that her opinions were "personal conjectures, not the result of essential scientific analysis," and "do not constitute objective, unbiased opinions based upon valid scientific data and method, and would not withstand review by a qualified panel of her peers."[48]

• • • •

Whatever such opinions are based on, it is not science. They are no more helpful to a factfinder than the conjecture of a passerby on the street. But if uttered from the lips of an "expert," they are likely to be valued as much more. The Federal Rules of Evidence expect such gross abuses of the invitation to expert witnesses to be screened out by trial judges, as these were. That screening, like other evidentiary rulings, should not be encumbered with costly procedural obstacles. This Court should not render any decision that could be interpreted as forbidding trial judges from continuing to perform that role so essential to the integrity and reliability of the factfinding process.

CONCLUSION

For the reasons stated, the judgment should be affirmed.

Respectfully submitted,

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January 19, 1993

[48] P.A. 3329-30, 4052, 4094, 4917-21, 5140-43, 5156, 5160-61, 5415-20, 5813-16 (Deborah Barsotti, Ph.D.).

ADDENDUM

ADDENDUM

The Federal Rules of Evidence provide in part:

Rule 104

Preliminary Questions

(a) Questions of Admissibility Generally. Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges. . . .

Rule 401

Definition of "Relevant Evidence"

"Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.

Rule 402

Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible

All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Rule 403

Exclusion of Relevant Evidence on Grounds of Prejudice, Confusion, or Waste of Time

Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger

of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

Rule 602

Lack of Personal Knowledge

A witness may not testify to a matter unless evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter. Evidence to prove personal knowledge may, but need not, consist of the witness' own testimony. This rule is subject to the provisions of Rule 703, relating to opinion testimony by expert witnesses.

Rule 701

Opinion Testimony by Lay Witnesses

If the witness is not testifying as an expert, the witness' testimony in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness and (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue.

Rule 702

Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Rule 703

Bases of Opinion Testimony by Experts

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before

the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Rule 704

Opinion on Ultimate Issue

(a) Except as provided in subdivision (b), testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.

(b) No expert witness testifying with respect to the mental state or condition of a defendant in a criminal case may state an opinion or inference as to whether the defendant did or did not have the mental state or condition constituting an element of the crime charged or of a defense thereto. Such ultimate issues are matters for the trier of fact alone.

Rule 705

Disclosure of Facts or Data Underlying Expert Opinion

The expert may testify in terms of opinion or inference and give reasons therefor without prior disclosure of the underlying facts or data, unless the court requires otherwise. The expert may in any event be required to disclose the underlying facts or data on cross-examination.

Rule 1101

Applicability of Rules

* * * *

(d) Rules inapplicable. The rules (other than with respect to privileges) do not apply in the following situations:

(1) Preliminary questions of fact. The determination of questions of fact preliminary to admissibility of evidence when the issue is to be determined by the court under rule 104.

* * * *

Supreme Court, U.S.
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No. 92-102

IN THE
Supreme Court of the United States
OCTOBER TERM, 1992

WILLIAM DAUBERT and JOYCE DAUBERT,
Individually and as Guardians Ad Litem for
JASON DAUBERT, and ANITA DE YOUNG, Individually
and as Guardian Ad Litem for ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

**On Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit**

BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC., NATIONAL ASSOCIATION OF MANUFACTURERS, BUSINESS ROUNDTABLE, AND CHEMICAL MANUFACTURERS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

Whether the Federal Rules of Evidence exclude from evidence scientific expert testimony which is not based on accepted scientific methods.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

No. 92-102

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC., NATIONAL ASSOCIATION OF MANUFACTURERS, BUSINESS ROUNDTABLE, AND CHEMICAL MANUFACTURERS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

INTEREST OF *AMICI CURIAE*

The Product Liability Advisory Council, Inc. is an association of industrial companies formed for the purpose of submitting *amicus curiae* briefs in appellate cases involving significant issues affecting the law of product liability. Its members include about 100 major manufacturers.

The National Association of Manufacturers of the United States of America is a non-profit voluntary business association representing more than 12,000 companies throughout the United States. NAM is affiliated with an additional 128,000 businesses through the National Industrial Council and the NAM Associations Council. NAM members are parties in cases nationwide and are interested in the fair administration of justice, which includes the appropriate use of scientific testimony.

The Business Roundtable is an association of the chief executive officers of approximately 200 of the largest companies in the nation. The Roundtable examines public issues that affect the economy and develops positions that seek to reflect sound economic and social policies.

The Chemical Manufacturers Association is a non-profit trade association whose member companies produce, market, and use industrial chemicals. Its members comprise more than 90 percent of the productive capacity for basic industrial chemicals in the United States.

This case is of paramount interest to *amici* because it illustrates the acute dangers to businesses and to society posed by the unchecked use of aberrant scientific testimony in the courtroom. While the district and appellate courts below acted properly in this case to filter out such testimony, other courts have not been so vigilant. The predictable result has been that businesses like respondent have abandoned the development of promising innovations and groundbreaking products because of the fear of unsound science in the courtroom and the enormous litigation risks this scenario presents. As principal voices of the business and manufacturing communities, *amici* are well suited to emphasize for the Court the impact of aberrant expert testimony on private litigants, and the need for courts to exercise responsible control over what is allowed to pass before juries in the guise of "expert" testimony.*

* Pursuant to Rule 37, letters of consent have been filed with the Clerk of the Court.

INTRODUCTION AND SUMMARY OF ARGUMENT

Judge Learned Hand once made an observation that goes to the heart of this case:

> No one will deny that the law should in some way effectively use expert knowledge wherever it will aid in settling disputes. The only question is as to how it can do so best.[1]

Amici submit that the Federal Rules of Evidence exclude expert scientific testimony when it has been developed without regard for accepted scientific methods. That is the precise situation in this case.

This case focuses on expert scientific evidence. Such evidence plays a vital and often dispositive role in modern litigation. For scientific evidence to be helpful to the factfinder it must meet some minimal threshold of reliability. To hold otherwise would be to allow a system of adjudication based more on chance than on reason.

An essential element of our system of dispute resolution is the principle that judgments reached in accordance with reliable evidence will promote accuracy and avoid mere speculation. The putative expert who offers to testify about issues of science without regard to the scientific method imperils the very foundation of rational decision-making. It is neither practical nor sufficient to rely on the give-and-take of cross examination to correct for expert scientific evidence offered without sound foundation. Indeed, admitting the testimony of experts whose methodology falls well outside the scientific mainstream undermines faith in our system of justice, deters investment in new technologies, and results in unwarranted judgments. This proceeding presents a chief case in point: respondent ceased distributing domestically the drug Bendectin in order to curb litigation expenses asso-

[1] Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 Harv. L. Rev. 40, 40 (1902).

ciated with that product, even though study upon study has now concluded that the attack on Bendectin was scientifically unfounded.

Amici believe that a rational system of dispute resolution requires that federal courts exercise their express authority under the Federal Rules of Evidence to scrutinize and monitor the quality of expert testimony, especially where, as here, that testimony is at odds with a rich and voluminous body of scientific literature. *Amici* support fully the development of innovative science, and believe that the Rules must be construed so as to impose standards for expert testimony which are not so high as to stifle this development, but not so low as to permit the introduction of aberrant science in the courtroom. The federal courts should use reliable science to help resolve legal disputes; they should not be asked to rewrite science.

In keeping with this Court's rules on *amicus* practice, this brief will not address issues that have been or are likely to be raised by the briefs of the parties or other *amici*, but will focus instead on four matters pertinent to this case but not likely to be fully addressed elsewhere. Part I demonstrates that experts have historically been afforded uncommonly wide testimonial latitude, and that this latitude has historically and necessarily been circumscribed by a series of "gateways," reaffirmed by the Federal Rules of Evidence, which protect the judicial process and ensure rational decision-making. Part II refutes petitioners' suggestion that the "adversarial system"—and, in particular, the availability of cross-examination—is an adequate check on unsound expert testimony, and the related contention that the Federal Rules of Evidence reflect a congressional determination to substitute the adversarial system for the courts' historic responsibility to determine whether a particular expert may testify at all. Part III explains why petitioners' attempted comparison between the use of scientific evidence in the administrative context and in the courts is flawed. Finally, Part IV explains that the courts below correctly excluded petitioners' proffered "scientific" testimony because under the Federal Rules of Evidence, such testimony must be developed according to the scientific method.

ARGUMENT

I. OUR JUDICIAL SYSTEM VESTS SUBSTANTIAL RESPONSIBILITY IN THE COURTS TO CIRCUMSCRIBE EXPERT TESTIMONY

Petitioners have brought this case claiming that the Federal Rules of Evidence were enacted to "limit judicial creativity" (Petitioners' Brief at 25), and to leave courts with little or no authority to fashion or apply guidelines as may be necessary to circumscribe expert testimony. As shown below, petitioners' vision of a neutered judiciary, forced to indulge most any expert testimony, ignores the wide latitude historically afforded experts in our judicial system. The vast scope of this latitude is shown in Part A below. This latitude has in turn fostered checks or "gateways" which logically and historically have been found necessary to limit such testimony. Part B shows that these limits are embodied in the Federal Rules of Evidence.

A. Experts Are Afforded Testimonial Latitude Well Beyond That Afforded Lay Witnesses

Petitioners' analysis initially fails to take account of the extraordinary latitude afforded experts in our scheme of justice. In critical respects, experts, despite their central role in modern litigation, are freed from the substantial constraints imposed on their lay counterparts.

1. *Experts are Free to Render Opinions Not Based on Firsthand Knowledge.* The rule that experts are free to render opinions based on other than firsthand knowledge has long distinguished expert from lay testimony. One of the earliest rules of exclusion at common law held that

witnesses could only testify as to matters within their personal knowledge.[2] An early scholar summarized the state of the law on this point:

> A witness examined as to facts ought to state those only of which he has had personal knowledge . . . . It has been said that a witness must not be examined in chief as to his *belief* or *persuasion*, but only as to his knowledge of the fact . . . . As far as regards mere belief or persuasion which does not rest upon a sufficient and legal foundation, this position is correct,—as where a man believes a fact to be true merely because he has heard it said to be so.

Thomas Starkie, *Evidence* 173 (1824). In essence, then, the so-called "opinion rule" originated as a rule that precluded witnesses from testifying about matters about which they had no knowledge or personal acquaintance. It was, in effect, a "gateway" that precluded certain individuals from testifying at all, or, in Wigmore's words, "merely a recognition of an otherwise established general principle of testimonial qualifications that the witness, to be competent at all, must have personal observation. Had the matter gone no farther, there would have been no separate 'opinion rule,' but merely a special application of an ordinary principle of testimonial competency." 7 John H. Wigmore, *Evidence in Trials at Common Law* § 1917, at 3 (Chadbourn rev. 1978) (citations omitted).

This principle finds full expression in Rule 702 of the Federal Rules of Evidence, which permits an expert to "testify . . . in the form of an opinion or otherwise," and in Rule 703, which permits experts to testify based on information which is simply "made known" to the expert "at or before the hearing." By contrast, Rule 701 continues to require that the opinion of a lay witness be "based on the perception of the witness" and be "helpful to a clear understanding of the witness' testimony."

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[2] This was also a general rule of civil and canon law. *See* William S. Holdsworth, 9 *A History of English Law* 211 n.4 (1926).

2. *Experts Can Testify About Otherwise Inadmissible Hearsay.* The evidentiary rule most frequently associated with the Anglo-American system is the ban on most forms of hearsay testimony.[3] The modern rule, as embodied in Rule 802, is premised on the notion that such evidence is inherently untrustworthy, in large part because it is not amenable to cross-examination.

In salient respects, however, this rule does *not* apply to experts. For instance, Federal Rule 803(18) permits experts to testify about statements contained in published works that are established to be reliable authorities. And Rule 703 permits an expert to base an opinion on facts or data that may otherwise be inadmissible if they are of a type reasonably relied upon by experts in the particular field.

3. *Experts Can Respond to Hypothetical Questions.* At common law and under the Federal Rules, only experts are permitted to respond to hypothetical questions. 2 Wigmore, *supra*, § 679. Prior to enactment of the Federal Rules, however, some courts had required that a hypothetical question (1) include all relevant facts, (2) omit any facts that were not supported or not likely to be supported by evidence before the trier of fact, and (3) be stated in open court. Charles T. McCormick, *McCormick on Evidence* § 14, at 37-38 (Edward W. Cleary *et al.* eds., 3d ed. 1984); 32 C.J.S. *Evidence* § 552 (1964). The Federal Rules liberalized the restrictions on hypothetical questions which may be asked of an expert. The combination of Rules 702, 703 and 705 enables counsel to ask hypothetical questions that incorporate facts or

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[3] Even before there was a generalized rule excluding hearsay, such evidence was viewed as inferior. The push toward adoption of a rule excluding hearsay came in part from a number of celebrated trials during the early sixteenth century in which obvious injustice was wrought by reliance on hearsay. *See generally* Richard O. Lempert & Stephen A. Saltzburg, *A Modern Approach to Evidence* (2d ed. 1983).

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data not actually in evidence, and which need not be disclosed during examination; they can be given to the expert in the secrecy of the office of the counsel who will present him.

4. *Experts Can Testify About Ultimate Issues.* Both the power, and potential danger, of expert testimony lie in large part in the expert's authority to draw conclusions concerning ultimate issues to be decided by the jury. The fact that such testimony arguably invades the province of the factfinder once led many states to exclude such expert opinions in their state court systems. *McCormick on Evidence, supra,* § 12, at 30. The Federal Rules, by contrast, expressly allow testimony on ultimate issues, save in criminal actions where defendant's mental state is an ultimate issue. *See* Fed. R. Evid. 704.[4]

As shown by these examples—of which there are others[5]—many of the fundamental rules of exclusion that promote the reliability of evidence simply do not pertain to experts, notwithstanding that their status in litigation commonly makes experts "as often skillful and effective in producing obscurity and error, as in the elucidation of truth." *McCormick v. Talcott,* 61 U.S. (20 How.) 402, 409 (1857) (Daniels, J., dissenting).

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[4] Federal Rule 704 applies to lay opinions as well as expert opinions. However, lay opinions are governed by the constraint set forth in Rule 701, requiring personal knowledge, and therefore are less likely to be admitted than expert opinions on the ultimate issue.

[5] For instance, experts also are not required to disclose during direct examination the facts or data underlying their opinions (Fed. R. Evid. 705), and can testify about matters that they learn from other witnesses during trial (Fed. R. Evid. 703).

B. The Federal Rules Of Evidence Reimpose Certain Historic Gateways As Necessary Checks On Expert Testimony

Given the extraordinary latitude traditionally afforded expert witnesses, courts and commentators have long recognized the need to impose "gateways" through which expert testimony must pass for it to be considered useful, and ultimately admissible, at trial. At the same time, it has never been thought that any single mechanism could be counted on to rein in expert evidence and curb unsound expert practices. Rather, courts have relied on the fashioning of appropriate principles governing the proper use of expert testimony, coupled with the trial court's exercise of its historic discretion to control the conduct of trials and to see to the proper and fair administration of justice. The so-called *Frye* test is a natural outgrowth of this legacy. *See* Paul Giannelli, *The Admissibility of Novel Scientific Evidence:* Frye v. United States, *A Half Century Later,* 80 Colum. L. Rev. 1197 (1980).

Far from renouncing this legacy—as petitioners suggest—the Federal Rules of Evidence support and reaffirm it. At the heart of the Federal Rules lies the proposition that the federal courts have both the authority and responsibility to employ rules of exclusion and evidentiary limitations to promote the reliability of testimony, whether lay or expert, all to "the end that the truth may be ascertained and [the] proceedings justly determined." Fed R. Evid. 102. The Federal Rules thus outline a series of "gateways" through which proper expert testimony must pass, and which together are intended to assist courts in distinguishing the useful from the useless, the meaningful from the misleading, and the probative from the prejudicial expert testimony.

In particular, the gateways embodied in Rule 702 (permitting scientific testimony only if it is based on "scientific . . . knowledge [that] will assist the trier of

fact"), Rule 703 (requiring that the underpinnings of an expert's opinion be "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject"), Rule 704 (requiring that opinions on the ultimate issue be "otherwise admissible"), and Rule 403 (excluding relevant testimony if it will, among other things, mislead the jury) provide a flexible yet cohesive scheme for "filtering out" expert opinions which are not firmly rooted in appropriate methodology —which, in the case of scientific testimony, means opinions not rooted in the scientific method. Simply stated, an expert's opinion on an issue of science which is developed without regard to the scientific method cannot constitute "scientific" knowledge within the meaning of Rule 702, and therefore can only "mislead[]," "confus[e]," and "prejudice" the factfinder as those terms are used in Rule 403. Evidence which appears to be scientifically objective, but which in reality is not, cannot "assist the trier of fact" as Rule 702 requires. The Ninth Circuit properly applied such constraints on expert testimony in excluding petitioners' scientific testimony.

II. THE FEDERAL RULES OF EVIDENCE NEITHER REQUIRE NOR PERMIT COURTS TO ABDICATE THEIR HISTORIC RESPONSIBILITY TO CIRCUMSCRIBE EXPERT TESTIMONY

Petitioners suggest that the Federal Rules of Evidence reflect a determination by Congress to "let it all in"—that is, to impose few if any constraints on the admissibility of expert testimony in the first instance, and to rely on the adversarial system for weeding out unsound scientific testimony and methodology. Petitioners' Brief at 15, 39-40. This view reflects not only a misreading of the terms and spirit of the Federal Rules, but a naive assessment of the potency of unsound scientific evidence in the courtroom.

A. Cross-Examination Is Not A Meaningful Substitute For Judicial Scrutiny

Few would deny that in many situations, cross-examination is an effective constraint on aberrant testimony. Effective cross-examination, however, presupposes that the jury will be able to understand the testimony and thus appreciate the weaknesses made evident during cross-examination.[6] There is no such presupposition in the context of expert testimony. To the contrary, the very reason for permitting expert testimony in the first place suggests that lay factfinders may not be able to fully comprehend and evaluate the testimony before them. This inability to fully appreciate scientific evidence can arise even in relatively straightforward cases, and can often lead a factfinder to embrace the fallacy that because one development follows another, the two are causally related.[7]

Concern over the ability of lay factfinders to fully comprehend complex expert evidence is not new. Learned Hand astutely highlighted the conundrum when he wrote:

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[6] Effective cross-examination also presupposes that attorneys will have ample opportunity to take discovery sufficient to conduct effective cross-examination. Yet federal discovery rules substantially restrict the opportunities and methods for discovering experts. Furthermore, recent amendments to the Federal Rules of Civil Procedure curtail the ability of parties to fully discover each other's experts. *See* Paul F. Rothstein, *The Collision Between New Discovery Amendments and Expert Testimony Rules*, Litigation, Spring 1988, at 17. And, of course, in criminal cases there is virtually no discovery.

[7] With such *post hoc* reasoning, one concludes that because event A preceded event B, it must have caused event B. For example, we may see an eclipse of the sun. We then beat on a drum. The eclipse disappears and the sun is restored. We conclude that beating the drum caused the sun to reappear. Alvan R. Feinstein, *Clinical Epidemiology: The Architecture of Clinical Research* 41-42 (1985). Scientific research is designed to avoid the *post hoc* fallacy.

> The whole object of the expert is to tell the jury, not facts, as we have seen, but general truths derived from his specialized experience. But how can the jury judge between two statements each founded upon an experience confessedly foreign in kind to their own? It is just because they are incompetent for such a task that the expert is necessary at all.

Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 Harv. L. Rev. 40, 54 (1902). This concern is all the more warranted as science-driven disputes increasingly wend their way through the federal courts. The burden on jurors is especially acute where, as here, they are asked to determine causation based on a reanalysis of epidemiological data culled *ad hoc* from a variety of previously published studies all of which point in the direction of no causation.[8]

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[8] In a sobering study, Dr. Molly Treadway Johnson, now of the Federal Judicial Center, sought to determine experimentally the ability of lay jurors to comprehend epidemiological evidence bearing on causation. Molly Treadway, *An Investigation of Juror Comprehension of Statistical Proof of Causation* (1990) (unpublished Ph.D. dissertation, Johns Hopkins University). In one experiment, 25 jurors who had been called for jury duty in Baltimore state court were shown two sets of epidemiological data and were asked to answer four questions about those data (*e.g.*, whether the results of the study indicate that being exposed to a given substance increases a person's risk of developing a certain abnormality). Out of 100 yes-no responses, only 41 were correct and only two subjects (or eight percent) answered all four questions correctly. In short, subjects performed worse than chance. In a second experiment, Dr. Johnson exposed one group of 30 jurors to a videotaped, simulated deposition in which an epidemiologist was being questioned by a lawyer. The tape was designed to teach the jurors how to use epidemiological information. A second group of 15 jurors was not shown the tape. Overall, only three subjects answered all four questions correctly. Dr. Johnson found that "there was no difference . . . between the expert and no-expert groups in terms of the number of subjects who used a correct approach at least once." *Id.* at 82-83. "It appears, then, that the expert testimony did not provide subjects with an understanding of how to analyze and interpret epidemiological data." *Id.* at 83. She concluded that

> [t]he results of Experiments 1 and 2 paint a rather dismal picture of lay jurors' abilities to understand epidemiological analysis. Subjects began with a poor understanding of epidemiological reasoning, and apparently were not helped when provided with expert testimony. Thus, the initial question of whether lay jurors are generally capable of understanding statistical proof of causation as it is presented under the current system must be answered in the negative.

Id. at 88.

Beyond the jury's lack of competence in many circumstances to evaluate the success of cross-examination, the very mystique of science is such that its admission alone may prejudice the opponent's opportunity for a fair trial beyond the curative powers of cross-examination. Even staunch advocates of the "let it all in" approach, such as Professor Tribe, acknowledge that

> the very mystery that surrounds mathematical arguments—the relative obscurity that makes them at once impenetrable by the layman and impressive to him—creates a continuing risk that he will give such arguments a credence they may not deserve and a weight they cannot logically claim.

Laurence H. Tribe, *Trial by Mathematics: Precision and Ritual in the Legal Process*, 84 Harv. L. Rev. 1329, 1334 (1971).[9] This is only to acknowledge that scientific studies have an inherent aura about them which, if not properly checked, can "assume a posture of mystic infallibility in the eyes of a jury of laymen," *United States v. Addison*, 498 F.2d 741, 744 (D.C. Cir. 1974),

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[9] Professor Tribe was writing in part about *People v. Collins*, 438 P.2d 33, 33 (Cal. 1968), where the California Supreme Court, in reversing a conviction based on the erroneous mathematical reasoning of an expert witness, warned that "[m]athematics, a veritable sorcerer in our computerized society, while assisting the trier of fact in the search for truth, must not cast a spell over him."

with the result that jury decisions may clash with "generally accepted scientific understandings." Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 Harv. L. Rev. 773, 780 (1990).

Furthermore, the rigid "let it all in" philosophy espoused by petitioners would impose enormous costs on society, on parties to litigation, and on our system of justice. When no or unduly low standards on expert participation are imposed in the first instance, the testimony that results will often be of little or no evidentiary value, yet may still consume vast amounts of the courts' and the parties' resources. *See Winans v. New York & Erie R.R. Co.*, 62 U.S. (21 How.) 88, 101 (1858). Moreover, excessive leniency in permitting the introduction into court of "science," however dubious its methodology, leads companies to question the wisdom of carrying on with the development of novel products which may invite courtroom attack.

If jurors have difficulty understanding epidemiological and other scientific evidence, it is unrealistic to presume that cross-examination, no matter how skillfully conducted, can remedy the use of unsound expert evidence. In such a setting, the imposition of reasonable gateways is imperative.

B. The Federal Rules of Evidence Neither Require Nor Countenance Slavish Reliance On The Adversarial System To Weed Out Unsound Expert Testimony

The position embraced by petitioners not only overstates the efficacy of the adversarial system in weeding out unsound expert evidence, but reflects a misreading of the Federal Rules. In particular, this view is in error because it reads the Rules piecemeal and out of context, rather than as a matrix of interdependent rules of exclusion. The Advisory Committee notes make clear that Congress envisioned that the courts would apply the

Rules not in isolation but as a cohesive code. Thus, in introducing Rule 704 permitting opinion testimony on ultimate issues, the Committee noted:

> The abolition of the ultimate issue rule does not lower the bars so as to admit all opinions. Under Rules 701 and 702, opinions must be helpful to the trier of fact, and Rule 403 provides for exclusion of evidence which wastes time. These provisions afford ample assurances against the admission of opinions which would merely tell the jury what result to reach . . . . They also stand ready to exclude opinions phrased in terms of inadequately explored legal criteria.

In practice, federal courts have applied the Federal Rules of Evidence as a *code*, mindful of its conceptual unity.[10]

The "let it all in" approach also overlooks the express mandate that the Rules be construed so as to "secure fairness in administration" and "elimination of unjustifiable expense and delay." Fed. R. Evid. 102. As noted above, unjustified expense and delay would be the predictable result were the Federal Rules construed, as petitioners suggest, to eliminate the authority of trial courts to apply rules of exclusion so as to filter out "misleading" evidence of no "assist[ance]" to the trier of fact.

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[10] *See, e.g., United States v. Schatzle*, 901 F.2d 252, 257 (2d Cir. 1990) ("[a]lthough the Federal Rules of Evidence do not bar all expert testimony concerning an ultimate issue . . . a district court may exclude ultimate issue testimony under Federal Rule of Evidence 702 when it is not helpful to the jury, or under Rule 403 when it may be unduly prejudicial"); *United States v. Scavo*, 593 F.2d 837, 844 (8th Cir. 1979); *United States v. Brown*, 776 F.2d 397, 401 (2d Cir. 1985), *cert. denied*, 475 U.S. 1141 (1986) (though expert testimony was not barred by Rule 704(b), "district judges should heed the Advisory Committee's Note to Rule 704" and also consider other "precautionary observations about the admission of [expert] testimony").

III. PETITIONERS' ANALOGY TO THE USE OF SCIENTIFIC EVIDENCE BY ADMINISTRATIVE AGENCIES IS UNTENABLE

Petitioners and certain *amici* challenge the conclusion of the Ninth Circuit because various federal agencies are willing to take regulatory action based on unpublished scientific research or in the absence of positive epidemiological studies. *See, e.g.*, Petitioners' Brief at 12 n.39; Brief of *Amici Curiae* of Physicians, Scientists and Historians of Science in Support of Petitioners at 18; Brief of *Amici Curiae* American Society of Law, Medicine and Ethics *et al.* at 10. In fact, the actions of federal regulatory agencies are not germane to the issues raised in this case for several reasons.

First, if procedures used by those agencies to assess risks were applied here, petitioners' claims would vanish. Simply stated, the United States Food and Drug Administration, the premier agency in assessing the safety and efficacy of drugs, has already determined that Bendectin is "safe" and "effective." *See* Federal Food, Drug, and Cosmetic Act § 505(b), 21 U.S.C. § 355(b) (1988) (setting forth prerequisites for FDA approval).

Moreover, petitioners overlook the differences between administrative "risk assessment" and judicial factfinding. Administrative action is aimed at regulating *future* conduct. *See, e.g., Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). The statutory missions of federal agencies include apprising the public of perceived future risks and setting standards to reduce such risks. For example, the National Toxicology Program lists a substance in the Annual Report on Carcinogens if that substance is "reasonably . . . anticipated to be [a] carcinogen[]." Public Health Service Act § 301(b)(4), 42 U.S.C. § 241(b)(4) (1988). The purpose of the Annual Report is risk identification, not resource reallocation.[11] However, the Program's listing does not penalize a manufacturer for *past* conduct. Regulatory action can be triggered even in the absence of an established cause-and-effect relationship. In sharp contrast, tort litigation judges past conduct, and shifts resources only where that past conduct *actually caused* the plaintiff's injuries.

In addition, the gateways so essential to the trial process for ensuring reasoned and consistent decision-making are not nearly as critical in the regulatory process. Unlike jurors, those making regulatory decisions often deal with scientific issues as part of their job, and are able to fully evaluate such evidence and ascertain potential risks. Moreover, since the decisions reached by agencies govern entire enterprises or lines of commerce, consistency is better assured. And finally, administrative agencies are expressly authorized to consider evidence that would ordinarily not be admissible in a court of law. *See* Administrative Procedure Act, 5 U.S.C. § 556(d) (1988) ("[a]ny oral or documentary evidence may be received" in administrative proceedings); *Richardson v. Perales*, 402 U.S. 389, 409 (1971); *McCormick on Evidence, supra*, § 352, at 1009 ("[a]dministrative agencies generally are not restricted in the kind of evidence they can admit").

In short, while one can draw meaningful lessons from the actions of administrative agencies that might be of

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[11] As such, a substance will be listed by the National Toxicology Program in the Annual Report even though there is no evidence of a cause-and-effect relationship between it and cancer; a mere association in animal studies will in the agency's view suffice. *See* Public Health Service, U.S. Dept. H.H.S., *Sixth Annual Report on Carcinogens* viii (1991). It bears noting that in spite of the Program's low threshold, "[o]nly substances for which the evidence of carcinogenicity has been peer-reviewed are evaluated for possible inclusion in the Annual Reports." *Id.* There is doubt, even within the agency, that this low threshold is consistent with the Program's statutory mandate. *See generally* Final Report of the Advisory Review by the National Toxicology Program Board of Scientific Counselors, 57 Fed. Reg. 31,721 (1992).

some use in the context of private litigation, the analogy pressed by petitioners goes too far. Administrative action is prophylactic and not retrospective; its purpose is to warn of possible health effects and not to judge whether a given agent in fact caused a specified ailment. Administrative action in the health sciences is undertaken by trained professionals pursuant to a statutory mandate, not by jurists and jurors. And administrative agencies, unlike federal courts, are not bound by the Federal Rules of Evidence.

What petitioners ultimately fail to acknowledge, then, is that legal systems fulfill a number of salutary purposes. They provide a socially acceptable means of resolving disputes, and lend a degree of certainty essential if people and enterprises are to invest in ideas and products. Fostering certainty, a fundamental goal of the Anglo-American system, is possible only where the rules that guide judicial decision-makers comport with those that guide responsible decision-makers in the private sector. Products developed through experimentation according to the rigors of the scientific method can be fairly judged only in light of that same method.

Petitioners' attempt to equate administrative and judicial action also obscures the fact that to condone tort liability based on opinions developed without regard to the scientific method increases uncertainty and, correspondingly, poses a significant disincentive to the development of new products. *See* Mahoney & Littlejohn, *Innovation on Trial: Punitive Damages Versus New Products*, 246 Science 1395, 1397 (1989) ("inhibiting effect of expanded product liability may permeate a firm's entire decision-making process"). This problem is particularly acute in the health care sector, where drug manufacturers

> might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to

> be marketed, because of the fear of large adverse monetary judgments. Further, the additional expense of insuring against such liability—assuming insurance would be available—and of research programs to reveal possible dangers not detectable by available scientific methods could place the cost of medication beyond the reach of those who need it most.

Brown v. Superior Court (Abbott Laboratories), 751 P.2d 470, 479 (Cal. 1988) (highlighting examples in which drugs and vaccines were withdrawn or not introduced because of liability concerns). In this regard, too, it is important to distinguish evidentiary rules that exclude aberrant testimony when judging past conduct from those rules used by administrative agencies in regulating future conduct.

IV. SCIENTIFIC EXPERT TESTIMONY MUST BE DEVELOPED IN ACCORD WITH THE SCIENTIFIC METHOD

This case shows the perils of unchecked expert testimony in the context of complex scientific evidence. For instance, the dangers inherent in permitting experts to offer opinions on ultimate issues were exemplified by the expert affidavits submitted to the district court by petitioners, which are rife with opinions about ultimate issues. Thus, Dr. John Palmer, although having never examined the Daubert or Schulier children or their mothers, nonetheless stated in his affidavit that "it is my opinion . . . that in each case the drug Bendectin was taken at the period of time such as to effect [sic] the cells that would produce the normal limb structure and that Bendectin did cause the limb defects in each of the children." J.A. 192. Such a conclusion, given its "scientific" underpinnings, is "likely to be shrouded with an aura of near infallibility, akin to the ancient oracle of Delphi" (*United States v. Alexander*, 526 F.2d 161, 168

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(8th Cir. 1975)), particularly given the jurors' predictable lack of facility for scientific information.[12]

Likewise, the rule permitting experts to answer hypothetical questions increases the likelihood that jurors will accept as true those "facts" that have been artfully incorporated into the question even though there is no evidentiary basis for accepting their validity.[13] This concern too was borne out in the case below when one of petitioners' experts, Dr. Swan, testified about "Type II errors" and concluded erroneously that there is an association between Bendectin and limb reductions.[14] Petitioners summarized her testimony as follows:

[12] In fact, one study revealed that 70 percent of attorneys and judges surveyed believed that juries accord scientific evidence more credibility than other evidence. Michael J. Saks & Richard Van Duizend, *The Use of Scientific Evidence in Litigation* 5-6 (1983) (citing results of O. Schroeder, *The Forensic Sciences in American Criminal Justice: A Legal Study Concerning the Forensic Sciences Personnel* (Forensic Sciences Foundation n.d.)).

[13] This is of more than hypothetical concern: a substantial body of literature suggests that individuals are influenced by information embedded in questions. In one study, subjects were shown a film of an automobile accident. Some were asked: "How fast was the white sports car going when it passed the barn while traveling along the country road?" No barn existed. Other subjects were asked the control question: "How fast was the white sports car going while traveling along the country road?" Subjects in the first group were significantly more likely to indicate the presence of the non-existent "barn" during follow-up questioning than were subjects in the second group. Elizabeth F. Loftus, *The Malleability of Human Memory*, 67 Am. Scientist 312, 312 (1979). *See* Elizabeth F. Loftus & David G. Miller, *Semantic Integration of Verbal Information into a Visual Memory*, 4 J. Exp. Psychol. 19 (1978); G.R. Potts, *Integrating New and Old Information*, 16 J. Verb. Learning & Verb. Behav. 305 (1977); Elizabeth F. Loftus, *Leading Questions and the Eyewitness Report*, 7 Cognitive Psychol. 560 (1975); Elizabeth F. Loftus & John C. Palmer, *Reconstruction of Automobile Destruction: An Example of the Interaction Between Language and Memory*, 13 J. Verb. Learning & Verb. Behav. 585 (1974).

[14] Epidemiologic studies involve consideration of two statistical possibilities: stating that a relationship exists when in fact it does not (Type I error), and failing to observe a relationship when one actually exists (Type II error). In the Bendectin studies, a Type I error occurs if a researcher erroneously concludes that Bendectin is associated with limb reductions, when in fact no relationship exists. In contrast, a Type II error is committed if the researcher concludes that there is no relationship between the drug and limb reductions when one actually exists.

> Dr. Swan calculated the risk of Type II error from the Bendectin studies and found, as to each study, that *even if Bendectin were causing a doubling of the incidence of human limb reductions* there was less than a 20% chance that the study would yield a "statistically significant" outcome if "significance" was [sic] defined as confidence at the 95% level.

Petitioners' Brief at 9-10 (footnote omitted). What petitioners neglect to note is that in order to calculate the probability of a Type II error one must *assume* an alternate hypothesis. *See* B.J. Winer, *Statistical Principles in Experimental Design* 11-14 (2d ed. 1971); Leonard M. Horowitz, *Elements of Statistics for Psychology and Education* 243-50 (1974). Thus, Dr. Swan *assumed* for purposes of her calculation that Bendectin *doubled* the risk of limb reductions. There is literally no evidence in the record, or anywhere else for that matter, that supports Dr. Swan's alternate hypothesis, *i.e.*, a doubling of the risk. Thus, while her testimony appears on its face to be highly probative, it in fact lacks evidentiary value.[15]

[15] As the Group of American Law Professors noted in their *amicus curiae* brief (at 22), "science subjects theories, hypotheses and common sense to systematic test." Dr. Swan's alternate hypothesis fails that test. If Bendectin in fact increased the risk of limb reductions by a factor of two and if, as a result, the probability of there being a Type II error were 80 percent, then one would expect that of the ten epidemiological studies dealing with limb reductions, eight would show a statistically significant association. In fact, none did. The probability that none would show a statistically significant association, given Dr. Swan's alternate hypothesis, is less than eleven percent. Dr. Swan also appeared to ignore one study in which researchers, after finding no associa-

In these and other respects, the Bendectin litigation shows what can go wrong when courts do not impose sufficient "gateways" governing the introduction of scientific expert testimony. The gateways embodied in the Federal Rules provide a series of threshold tests against which such scientific opinion must be measured. These tests have their roots both in the language of the Federal Rules and in the scientific method. We submit that the tenets of the scientific method articulate what amounts to a minimum universal standard against which all putative scientific opinion should be judged, a common denominator linking the *Frye* test and its various adaptations.

Opinion as to an ultimate fact developed without regard to the scientific method does not qualify as "scientific knowledge" as that term is used in Rule 702. Since it would not be relied upon by scientists in the field, it would not "assist the trier of fact" as required by Rule 702, or be said to be based on data or methodology "reasonably relied upon" by those in the field as required by Rule 703. Furthermore, since an opinion developed without regard to the scientific method appears to have scientific authority that it in fact does not have, it is "misleading" and "prejudic[ial]" within the meaning of Rule 403. This does not mean that novel scientific findings that diverge from accepted notions ought to be rejected. The scientific method does not denigrate novel results even where they may clash with commonly held beliefs. The scientific method speaks to the *process* by which the scientist reached a conclusion, not to the conclusion itself, thereby ensuring the orderly growth of knowledge. As such, the scientific method and the philosophy underlying the Federal Rules are both premised

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tion between Bendectin and limb reductions, stated that there was only an 18 percent chance of missing a two-fold increased risk to Bendectin-users, *i.e.*, the probability of a Type II error for the study was 18 percent. S. Morelock *et al.*, *Bendectin and Fetal Development: A Study at Boston City Hospital*, 142 Am. J. Obstet. & Gynecol. 209, 212 (1982).

ultimately on the same objective: the efficient search for truth. *See* Fed R. Evid. 102.

In particular, the scientific method [16] requires that one (1) first set forth a hypothesis,[17] (2) design an experiment, or more properly a set of experiments, to test the hypothesis,[18] (3) conduct the experiment, collect the data, and then analyze those data, (4) publish the results so that they may not only add to the body of knowledge, but also be subject to external scrutiny,[19] and (5) ensure that those results are replicable and verifiable.[20]

When judged against these standards, petitioners' proffered expert testimony fails to measure up. Petitioners did not negate the hypothesis that there is no association between Bendectin and limb reductions; did not establish any alternate hypothesis in accord with the scientific method; did not publish their work for proper peer review; and otherwise did not adhere to standard scientific methodology. Indeed, petitioners did little more than

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[16] The rudiments of the scientific method derive from the work of Bacon, Galileo and Newton. *See* Ernan McMullin, *The Development of Philosophy of Science 1600-1900*, Companion to the History of Modern Science 816 (R.C. Olby *et al.* eds., 1990). The pioneering work of British statistician Sir Ronald A. Fisher underlies the design of scientific experiments more generally. *See* Ronald A. Fisher, *The Design of Experiments* 11-26 (8th ed. 1966).

[17] *See* Martin Goldstein & Inge F. Goldstein, *How We Know: An Exploration of the Scientific Process* 19 (1978).

[18] *See* Francisco J. Ayala & Bert Black, *The Nature of Science and the Problem of Demarcation*, 1 Science and Courts 1 (forthcoming 1993).

[19] *See generally* John M. Ziman, *Reliable Knowledge: An Exploration of the Grounds for Belief in Science* (1978). *Cf. People v. Collins*, 405 N.Y.S.2d 365, 369 (Sup. Ct. 1978) (new theories must be "tested in the crucible of controlled experimentation and study," a procedure that requires "replication of original experiments, and scrutiny of the results in various scientific journals").

[20] *See* Karl R. Popper, *The Logic of Scientific Discovery* 44-45, 53-54 (rev. ed. 1972).

criticize the work of other scientists. But critiquing another's study does not validate one's own. Yet, under petitioners' conception of a shackled judiciary, such testimony—though it does not qualify as "scientific knowledge" capable of supporting their burden of proof—would nevertheless be presented to the jury.

When attempting to draw scientific conclusions, whether at the laboratory bench or the courtroom bar, one should at a minimum be required to formulate those conclusions in accord with the scientific method. That method provides a straightforward, relatively simple, and reasonable test for the admissibility of expert opinion. It is a test, moreover, which federal judges can readily apply, and which, in cases like this, would enable them to unearth the fallacies in unsound scientific evidence. It does not require the court to make value judgments about the legitimacy of the results, or to reject novel scientific conclusions merely because they are novel. Rather, it provides the court with guidance for measuring proffered evidence against a time-honored threshold, a threshold which simultaneously promotes novelty and reliability.

In sum, *amici* submit that the gateways reaffirmed by the Federal Rules of Evidence in effect incorporate the scientific method, and that the *Frye* test represents one appropriate way of adapting the scientific method to the courtroom setting.

CONCLUSION

Petitioners' expert testimony was properly excluded. The judgment below should be affirmed.

Respectfully submitted,

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No. 92-102

In The

Supreme Court of the United States

October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians ad litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian ad litem for ERIC SCHULLER,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF *AMICI CURIAE* OF NICOLAAS BLOEMBERGEN, ERMINIO COSTA, DUDLEY HERSCHBACH, JEROME KARLE, ARTHUR LANGER, WASSILY LEONTIEF, RICHARD S. LINDZEN, WILLIAM N. LIPSCOMB, DONALD B. LOURIA, JOHN B. LITTLE, A. ALAN MOGHISSI, BROOKE T. MOSSMAN, ROBERT NOLAN, ARNO A. PENZIAS, FREDERICK SEITZ, A. FREDERICK SPILHAUS, DIMITRIOS TRICHOPOULOS AND RICHARD WILSON IN SUPPORT OF RESPONDENTS

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IN THE

Supreme Court Of The United States

OCTOBER TERM, 1992

No. 92-102

WILLIAM DAUBERT and JOYCE DAUBERT,
Individually and As Guardians Ad Litem for
JASON DAUBERT, and ANITA DE YOUNG, Individually
and As Guardian Ad Litem
for ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF *AMICI CURIAE* OF NICOLAAS BLOEMBERGEN, ERMINIO COSTA, DUDLEY HERSCHBACH, JEROME KARLE, ARTHUR LANGER, WASSILY LEONTIEF, RICHARD S. LINDZEN, WILLIAM N. LIPSCOMB, DONALD B. LOURIA, JOHN B. LITTLE, A. ALAN MOGHISSI, BROOKE T. MOSSMAN, ROBERT NOLAN, ARNO A. PENZIAS, FREDERICK SEITZ, A. FREDERICK SPILHAUS, DIMITRIOS TRICHOPOULOS AND RICHARD WILSON IN SUPPORT OF RESPONDENTS

INTEREST OF *AMICI CURIAE*

Amici are eighteen scientists, scholars, and teachers of science. *Amici* include six Nobel Laureates -- Nicolaas Bloembergen in Physics, 1981; Dudley R. Herschbach, in Chemistry, 1986; Jerome Karle, in Chemistry, 1985; Wassily Leontief, in Economics, 1973; William N. Lipscomb, in Chemistry, 1976; Arno A. Penzias, in Physics, 1978. Several are recipients of the National Medal of Science and other distinguished prizes and awards in their respective fields. The fields of expertise of *amici* include chemistry, physics, meteorology, medicine (including, of particular relevance to this case, epidemiology, environmental medicine and teratology). Many of them are recipients of multiple honorary degrees in addition to earned doctorates in various fields of science. Many are or were editors and contributors to scientific and other scholarly journals, and are authors of authoritative works in their respective areas of expertise. Most are professors at several of the most highly regarded institutions of higher education in the United States, and one a former president of one of the most prestigious research universities in the world. They hold many other distinctions for achievements in fields of science and academia. *Amici* are authors of numerous articles, studies, monographs and textbooks. Many are frequently called upon to serve on official commissions, review boards, advisory committees and institutes[1].

Amici have no interest in the outcome of this case, any

[1]. The qualifications of *amici*, the positions they hold and have held, and the scholarly honors and distinctions they have earned are set forth in the appendix to this brief.

other "Bendectin case", or any case in which injury is allegedly caused by pharmaceuticals. We appear solely as individuals, on our own behalf, to inform the Court of our views as to the appropriate criteria for acceptable scientific evidence, and to respond to certain misconceptions that pervade some of the *amicus* briefs filed in support of Petitioners and which could adversely affect the judgment of this Court if uncorrected. Our interest transcends the issues in this case or the positions of any party[2].

SUMMARY OF ARGUMENT

The courts below strove to ensure that opinion testimony that was the result of methods of inquiry not generally accepted as valid in a particular field of scientific endeavor would not become the basis of decision by a jury of individuals with no particular knowledge or experience in scientific or technical matters. We believe that this effort is of great importance and the goal salutary. Scientific terminology and scholarly credentials can, and often do, have an inordinate effect on a lay person's perception of the authoritativeness of a scientist even when, or more precisely, just because, the lay person is usually not able to evaluate the intrinsic merit of the propositions advanced by the scientist. We do not suggest that scientists or other scholars belong to a caste superior to lay jurors, but we do believe that the scientific community as a whole is better able to evaluate the data and methods used by

[2]. Counsel for the parties have consented to the filing of this brief. Letters of consent have been filed with the Clerk of the Court.

scientists.

The impact and influence of scientific rhetoric can easily sway and mislead a jury. Opinion testimony based on scientific techniques or methodology that are not generally accepted by the scientific community is not reliably valid. Testimony must be based on facts or data reasonably relied upon by experts in a particular field[3]. Testimony not so grounded will not assist the trier of fact to understand critical facts in issue, and is more likely to mislead.

Publication and peer review, while not **guaranteeing** that particular methods of scientific investigation or data are accurate, are vital means of permitting the scientific community to see the data, to understand them, to test them, to evaluate the methods and show, either that the data or methods of a particular scientist are correct and appropriate and do lead to valid conclusions or, if such be the case, are not correct and thus do not lead to valid conclusions.

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[3]. We understand "particular field" to include cognate or associated disciplines of a specific field that may be relevant. Thus, in a case involving testimony regarding clinical medicine, such as a products liability litigation, related fields such as experimental pathology, biology, epidemiology, biostatistics, several specialties in physics or chemistry, industrial hygiene and others might be relevant.

ARGUMENT

I. PETITIONERS' ARGUMENTS AND THOSE OF CERTAIN *AMICI* IN SUPPORT OF PETITIONERS MISCONSTRUE THE PRINCIPLES APPLIED BY THE COURTS BELOW

The main thrust of Petitioners' factual presentation is, we submit, based on an incorrect reading of the decisions of the Court of Appeals for the Ninth Circuit and the District Court. Petitioners contend that the court of appeals and the district court excluded the affidavit and deposition testimony of plaintiffs' expert witnesses because those witnesses reached conclusions that were not "generally accepted" in the scientific community. Petitioners identify the "central issue in this case" to be whether the "rule...that expert scientific opinion evidence is inadmissible unless it has attained general acceptance in the relevant scientific field..." is the proper rule of evidence. [*See* Brief for Petitioners' (hereafter "Pet. Br.") at 14]

Neither the district court nor the court of appeals excluded the testimony of plaintiffs' experts because their opinions had not gained general acceptance. Rather, the court of appeals affirmed the dismissal because the methodology used by plaintiffs' key expert had not been demonstrated to be generally accepted as a reliable technique in the scientific community. [Joint Appendix (hereafter "JA") 238] As the court of appeals stated: "For expert opinion based on a given scientific methodology to be admissible, the methodology cannot diverge significantly from procedures accepted by recognized authorities in the field." [JA 239]

The district court excluded the testimony of plaintiffs' experts on two separate bases: first, that the epidemiological bases relied upon by plaintiffs' experts (which in fact were reanalyses of data collected by others that had been reported in published studies and that had reached a conclusion contrary to those of plaintiffs' experts) had not themselves been published or subject to peer review and second, that the published studies did not state that Bendectin increased the relative risk of limb reduction defects to a statistically significant level. [JA 232-236] Thus the district court did not exclude the evidence of plaintiffs' experts because the court disagreed with their conclusions, but because their epidemiological methodology had not been subjected to scrutiny by the scientific community and because their conclusions were legally insufficient.

The court of appeals also did not focus on the conclusions of plaintiffs' experts, but rather whether the methodology used is "generally accepted as a reliable technique," [JA 239].

Petitioners, based on their misreading of the decisions below, set up a straw man: that the courts below imposed publication and peer review as the *sine qua non* for admissibility of expert opinion. The court of appeals did not establish such a general rule, but instead found that the method of reanalysis of epidemiological studies employed by plaintiffs' experts would be generally accepted in the scientific community only when it has been subjected to scrutiny and verification by others. [JA 240-241]

Certain of Petitioners' *amici* likewise create strawmen.

Chubin, Hackett, Ozonoff and Clapp (hereafter "Chubin, *et al.*" or "the Chubin *amici*"), for example, incorrectly argue that the lower courts devised "two mischievous presumptions: an apparently rebuttable presumption that anything that is published in a peer review journal is "good science" and therefore admissible; and, conversely, an "evidently irrebuttable" presumption that unless a theory, fact, or analysis has been previously published in a peer-reviewed journal such ideas and information cannot be "good science" and cannot form the basis for admissible expert testimony. [Chubin Br. at 3]. If the courts below had in fact done that, we would not submit a brief supporting the judgment below. As shown *infra*, the process of publication and peer review merely leads to a rebuttable presumption of validity.

Amici "Physicians, Scientists and Historians of Science" (hereafter "Ronald Bayer, *et al.*") argue that "Judgments based on scientific evidence, whether made in a laboratory or a courtroom, are undermined by a categorical refusal even to consider research or views that contradict someone's notion of a prevailing 'consensus' of scientific opinion" [Bayer Br. at 2; emphasis supplied], and further that the courts below converted peer review into "a litmus test for scientific truth." [Bayer Br. at 3], and, finally, that the courts below acted like inquisitors, searching out and condemning "heresy"[4] [*e.g.*, Bayer Br. at 11, 14, 15], rather than forums for the discovery of "truth". These arguments do not address the issues genuinely before this Court, for the lower courts neither conducted inquisitions into

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[4]. We do not accept any such characterization or term as being relevant or appropriate in this context or bearing on a discussion of scientific methods.

"heresy", nor did they exclude evidence because the expert witness' conclusion contradicted some "consensus".

II. PUBLICATION AND PEER REVIEW ARE ESSENTIAL FOR DETERMINING WHETHER SCIENTIFIC PRINCIPLES OR METHODOLOGIES ARE ACCEPTED IN THE SCIENTIFIC COMMUNITY

Publication and peer review[5] are central to the scientific enterprise of corroborating or falsifying methods, data, theories and conclusions advanced by scientists to explain natural phenomena. We agree with Chubin, *et al.* that publication and peer review are not the final answer to the question of "What is truth?" While it is correct, as Chubin, *et al.* assert [Chubin Br. at 6], that peer review journals do not replicate and verify the experiments, research and analytical techniques, or data reported in the papers submitted for publication,[6] peer review does not end with publication -- publication is only a starting point of peer review. The function of publication is to make data and methods available to the scientific community beyond

[5]. Publication and peer review are not synonymous. Publication is merely one aspect of peer review. The Court of Appeals recognized the distinction: "These Courts [referring to the *Lynch* court and the *Richardson* court] were unwilling to allow plaintiff to rely on reanalyses of epidemiological studies because these studies had neither been published nor subjected to the rigors of peer review." 951 F.2d at 1130.

[6]. "Publication" is not, of course, limited to the appearance of articles in scholarly journals. It encompasses books, government reports, reports by private institutions or other mechanisms, such as published colloquia, proceedings of conferences or other means for disseminating information widely and making it available to other scientists.

the scientist's inner circle and beyond the editorial staff and referees of the journal: publication exposes the work to the scientific world at large, which then has the opportunity to replicate and confirm, or fail to replicate and falsify, the scientist's proposition. Of course, peer review journals do not "warrant" that the ideas or information contained in the articles they print are "accurate, valid, certain, reliable or true" [Chubin Br. at 6][7]. Indeed, scientists do not assert that they know what is immutably "true" -- they are committed to searching for new, temporary, theories to explain, as best they can, phenomena[8]. It is nothing more than a red herring to

[7]. We note that for all their criticism of the peer review process before publication, Chubin, *et al.* themselves illustrate the value of vetting during the publication process: they cite a report showing an increase in accuracy of statistical reports from 11% to 84% as a result of peer review publication. [Chubin Br. at 15] While Chubin and his colleagues deride an accuracy rate of 84%, and sarcastically wonder whether a truck driver or airplane pilot who got it right only 84% of the time deserves praise, it is certainly far better to "get it right" 84% of the time than only 11% of the time. It is uncertain whether courts can claim to get at the truth, in a philosophical sense, even that often.

[8]. Chubin, et al. are correct when they write "[T]he peer review system provides [an] extremely valuable service -- to furnish in a timely fashion, interim progress reports of ongoing research experiments, promising investigatory techniques and methodological protocols, useful analytical tools, interesting findings, or provocative hypotheses. The provisional nature of science "truths" is reflected in the fact that peer review journals welcome, and frequently publish, articles, comments, and letters to the editor that are critical of the initial article. Thus each article stands not as the final word on a given subject but as an invitation to or part of a continuing debate, a never-ending dialogue." [Chubin Br. at 8-9]. This proves our point. Publication is the starting point in the search for scientific "truth"; without it, the process cannot be advanced. And without it, the scientific community has no way of evaluating the "truth" of what a particular scientist or group of scientists asserts.

argue that peer review does not guarantee "truth"[9]. Of course, the "mere fact" of publication does not mean that the ideas and information reported in an article are generally accepted by, or represent the consensus views of, the relevant academic community. Again, publication is the first step in obtaining a (temporary) consensus: Without publication other scientists would be unaware of the idea and so there would never be a consensus.

We disagree strongly with the assertion of Chubin, *et al.* that the fact that ideas and information have not been published in a peer review journal does not mean that they are not generally accepted. While failure to publish does not imply that the ideas are "generally rejected", or that they cannot represent "good science", it does mean that the scientific community has not had the opportunity to test and confirm the "discoverer's" findings and ideas, or to satisfy itself that proper methods were used and that the methods and results represent "good science".

There is a major difference between the presentation of evidence for the sake of establishing "truth" in science on one hand and law on the other. Typically, in the legal process a

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[9]. Indeed, this is one of the prime differences between science and adjudication. Science acknowledges that it does not know the "truth", and that perception of "truth" will change with time. But in litigation, the process must determine the "truth" in a particular situation, at a particular time -- a dispute must be resolved with finality; the verdict is the "truth" in the utilitarian process of "fact finding". A corollary is that the law applies its standards of proof to resolve disputes; in science, on the other hand, standards of proof exist for the purpose of inducing agreement among scientists, and all issues remain open even after there is substantial agreement.

specific conclusion is the goal of the evidence offered. Thus there is a strong motivation to be selective because of bias. Quite often, the experiments will have been conducted with a pending case or at least potential litigation in mind. On the other hand, scientific journals are typically concerned with progress in a particular field, and in making progress with sound methodology. The journal will let the conclusions fall where they may. Individual scientists who might have an interest in reaching a particular conclusion at the expense of rigor in methodology are challenged in the peer review process. One important advantage of publication and peer review, as compared with cross-examination and contradictory testimony of the adversary's expert, is that peer review by the scientific community at large enables scientists who are truly disinterested in the outcome of a particular litigation, the prospects of a particular product, the financial success of a particular industry, or even "justice", will have the opportunity to test, evaluate and either confirm or refute data, findings or theories. We submit that this neutral process is of great value both in science and in the courts.

Certainly, without publication and subsequent peer review ideas cannot become "generally accepted". Indeed, the notions of confidentiality or "privilege" and "general acceptance" are antithetical. The court of appeals below was correct in remarking that the work of "experts" prepared for the specific purpose of litigation, and not published or peer reviewed, cannot be said with any confidence to utilize generally accepted principles and methods [JA 241, n.3].

Techniques can be considered widely accepted when

they are used to produce results that are accepted time and again for publication in reputable reviewed media. The publication once of a new technique, no matter how esteemed the reputation of the author or the journal, gives it no inherent validity. That first publication simply says the editor and reviewers feel the article is of interest and do not immediately see why the methodology or theory will not work. The consequent exposure, then, of the technique to the scientific community allows for discussion and hopefully its replication. Its continued use, and acceptance in peer review journals, provides some assurance of validity, but does not provide any guarantee.

When experts are asked to draw a conclusion in a courtroom, their expertise must be established. Acceptability is established in science when a scientist produces results that have appeared in peer review journals and have stood the test of subsequent challenges. Publication is not a sufficient test by itself.

Scientific "orthodoxy" should be tested in the laboratory, in the meeting rooms and hallways at scientific meetings and on the pages of journals, and not in the courtroom. Ronald Bayer, *et al.* use the term "good science" [Bayer Br. at 3 and *passim*]. "Good science" is science that is done well, not necessarily science that produces the desired results. It is impossible to determine what results are correct. In that sense, good science is that science that undergoes the scrutiny of peer review, not only in the publication process, but after publication, when the scientific community examines the published data, findings and theory and then tries to replicate

the data and the findings. Publication in a peer review medium is therefore a **necessary** but not **sufficient** condition.[10]

Contrary to the conclusion of the Chubin *amici*, we submit that because of the technical, and increasingly technical, nature of much of the expert testimony offered in court, the jury and the cross-examination process are not adequate to ensure that scientific evidence has been derived from facts or data generally relied on by experts in the field. Publication and peer review do serve that important purpose.

If the courts below had used a phrase such as "universally recognized scientific truths", as Petitioners and certain *amici* at least imply, they would have adopted a clearly unacceptable criterion. But that is not what the lower courts in this case did. They simply recognized the central role publication and peer review play in the process of detecting and reducing the use of "bad science" in litigation.

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[10]. It must be borne in mind that editors seek for their journals the controversial experiments and results that have been done well. It is these provocative papers that often stimulate new ideas and lead to the breakthroughs, although the success rate is not great.

Widespread publication is a fairly recent phenomenon, about 200 years old. In the latter half of the twentieth century, methods of communication have developed to the point that awareness of published scientific work is almost universal.

III. THERE ARE FUNDAMENTAL DIFFERENCES IN THE MEANING OF "TRUTH" IN THE LEGAL AND SCIENTIFIC REALMS

It is common ground, we believe, that in science accepted "truth" is not a constant: that it evolves, either gradually or discontinuously. As Sir Karl Popper, the preeminent philosopher of science has asserted, the scientific enterprise starts with a deductive method to derive hypotheses which are then tested by observation or experiment. Karl R. Popper, THE LOGIC OF SCIENTIFIC DISCOVERY 32 (1959). For a theory to be "scientific", it must set forth an hypothesis that is capable of being proven false by observation or experiment and the data produced through this testing must be capable of replication. *Id.* at 40-41, 46. An hypothesis can be falsified or disproved, but cannot, ultimately, be proven true because knowledge is always incomplete. An hypothesis that is tested and not falsified is corroborated, but not proved. Thus, scientific statements or theories are never final and are always subject to revision or rejection. *See* L. Loevinger, "Standards of Proof in Science and Law", 32 Jurimetrics J. 327 (1992), revised and corrected version in 18 INTERDISCIPLINARY SCIENCE REVIEWS (London 1993, in press) . On this, we agree with Bayer, *et al.* [*See* Bayer Br. at 9[11]] Replicability, which is noted by Popper and others as the hallmark and guarantee of

[11]. The statement by Sir Austin Bradford Hill in *Environment and Disease: Association or Causation?*, 58 Proceedings of the Royal Society of Medicine 295, 299-300 (1965), quoted by Bayer, *et al.* [Bayer Br. at 9] is another way of saying the same thing. The quotation from 1 Responsible Science: Ensuring the Integrity of the Research Process 38 (Nat'l Academy of Sciences 1992) [Bayer Br. at 9,n 6] is virtually identical with our position.

scientific acceptability, involves other scientists testing the accuracy of observations or of the predictions of an hypothesis. Scientific experiments are, of course, always expected to be replicable.

All of this is also relevant to law, since the basic principles of reasoning or logic are no different in the field of law than in science. However, the functions of law, and thus the propositions to be established by evidence and logic in the legal process, are quite different. While science involves an effort to construct a system of descriptive general theories based on particular data, law consists of a system of normative general rules that are individualized to apply to particular cases. This distinction engenders a number of significant differences.

An important difference between science and law is that the propositions to be tested in science are predictive while the facts to be proved in the legal process arise out of situations that occurred in the past and which cannot be repeated exactly[12]. The legal process rarely has the luxury of being

[12]. As Judge Easterbrook observed in *Branion v. Gramly*, 855 F.2d 1256, 1264 (7th Cir. 1988):

> Every event, if specified in detail, is extremely improbable; indeed, with *enough* detail it is unique in the history of the universe. It is always possible to take some probabilities, small to start with, and multiply them for effect. In order to avoid the errors produced by mindless multiplication, the statistician must specify with care what we should expect to find if the event in which we are interested has occurred,

able to repeat experimentally a disputed chain of causation to corroborate the proffered hypothesis, even if, in some cases, it might theoretically be possible.

The legal process of adjudication -- litigation -- has highly structured rules and devices concerning the reception of evidence and the proof of propositions, which largely determine the proof available to the finders of fact in particular cases. The rules of evidence in federal courts are now embodied in positive law, the Federal Rules of Evidence (with corresponding provisions in most states), as well as in jurisprudential precedents. We agree with Petitioners that the basic principle of the Federal Rules of Evidence can be stated simply: all relevant evidence is admissible, except as otherwise provided, while irrelevant evidence is not admissible. *See* Fed.R.Evid. 401, 402. But this apparent simplicity of structure, so heavily relied upon by Petitioners, is misleading. Nearly all the other rules of evidence are rules of exclusion on one ground or another[13].

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and what we should expect to find if it has not. Next we must develop criteria that might differentiate one from the other. Only then can we begin to assess probabilities. This can be a daunting task.

[13]. Relevant evidence may be excluded if the court believes that its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, misleading the jury, unnecessary delay or waste of time, or if it is merely cumulative. *See* Fed.R.Evid. 403. Character evidence is generally not admissible to prove conduct. Fed.R.Evid. 404. Offers to compromise a claim are generally not admissible. Fed.R.Evid. 408. Hearsay is generally not admissible, although there are at least two dozen exceptions to this exclusion. Fed.R.Evid. 802, 803(1)-(24). Numerous privileges may

The scientists on whose behalf this brief is filed believe that the Bayer brief, filed in support of Petitioners, although it may speak for one group of scientists, unfortunately embodies a fundamental misconception of the relationship between science and law, a misconception which permeates the brief and invalidates its conclusions. In its Summary of Argument, the Bayer brief states, *inter alia*: "Perpetuating the reign of a supposed scientific orthodoxy in this way [by using the Frye "rule"[14]], whether in a research laboratory or in a courtroom, is profoundly inimical to the search for truth." [Bayer Br. at 2] Throughout the Bayer brief there are similar expressions indicating a failure to distinguish between the purposes of science in the laboratory and scientific testimony in court. Indeed, the principal point of the Bayer brief is stated to be that "Scientific inquiry, like the fact finding process in the law, is undermined by a categorical refusal even to consider views or analysis that challenge the supposed conventional wisdom." [Bayer Br. at 7]

Much of the argument of the Bayer brief consists of a lengthy dissertation on the history and philosophy of science,

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silence a witness, including the privilege against self-incrimination, the spousal privilege, and privileges protecting disclosures made to an attorney, doctor, or clergy. In addition, there are rules regarding the "burden of proof" and presumptions that operate in the absence of evidence on an issue or when the evidence is equally balanced.

[14]. The court of appeals below did not, of course, rely on the "Frye rule", as Petitioners assume throughout their brief, and as do virtually all of the *amici* who have filed briefs in support of Petitioners. While the result below, and the principle articulated in this brief, are consistent with the "Frye rule", they are based on the Federal Rules of Evidence, specifically Rules 702 and 703.

a good part of which is correct in its original context, as when the Bayer brief states that "Galileo was persecuted by the Inquisition for challenging the geocentric orthodoxy promoted by the Aristotelian scientists who dominated the academies and universities." [Bayer Br. at 14] However, this, and numerous other examples of scientific theories, perhaps once called heresies, which have now become accepted as true, with which Bayer and his colleagues regale us, are quite irrelevant to the issues confronting United States courts in the twentieth century. Galileo was prosecuted by ecclesiastical authorities in the seventeenth century, and was ordered not to write in support of the Copernican theory. The ecclesiastical authorities claimed to know "the truth" and asserted moral and divine authority to ban heresy. But United States courts do not have, and do not assert or claim to have, any authority whatsoever over the publication or promulgation of scientific observations, data or theories, and are not at all concerned with "heresy". A rule excluding expert testimony in litigation would not inhibit any new Galileo.

There are two distinctly different areas of activity and authority which are mistakenly treated as one by the Bayer brief. First, there is the process of scientific research and publication which concerns the formulation, corroboration, and advancement of scientific principles and theories. The corpus of this work constitutes the fields called "science"; and progress in science depends entirely and exclusively upon the activities and opinions of scientists. Second, there is an entirely separate area, which is the field of legal process that concerns the adjudication of rights between particular parties. In the course of litigation issues arise involving the admissibility of certain

types of evidence from many fields, including science; but the legal process does not establish nor attempt to establish scientific theories, principles or "truth" for the purposes of science, but only for the purposes of adjudication.

A critical difference is that while in science it is recognized that "truth" is extremely mutable, in adjudication "truth" for the limited purpose of resolving disputes must become final and immutable in a relatively short time. This concept of finality -- essential to adjudication -- is completely foreign to science.

The standards for the reception of evidence by courts in the course of adjudication are thus not the same as the standards that scientists use in accepting or rejecting new data or theories. Indeed, there are many fields of science with varying standards regarding both observations and theories; and there are scientific theories that many scientists accept for purposes of inquiry, investigation, and calculation that have literally no evidentiary support. *See, e.g.*, Roger Penrose, THE EMPEROR'S NEW MIND 152-155 (1989).

On the other hand, in adjudication the law establishes its own standards of precision and reliability, and mandates that the "truth" be determined from admissible evidence.

With respect to scientific matters, a witness who is qualified as an expert in a relevant field may state his conclusions as to scientific knowledge, Fed.R.Evid. 702, provided that his conclusions are based on facts or data directly observed by him or are of a type reasonably relied upon by

other experts in the same field. Fed.R.Evid. 703. That is basically what the rule adopted by the circuit court in this case requires. The rule applied by the courts below does not require that the conclusions reached by a scientific expert be generally acceptable, but it does require that the scientific principles and the methodology upon which conclusions are based must have gained acceptance in the relevant scientific field to be admissible.

It is a complete *non sequitur*, and false, to suggest, as the Bayer brief does, that the refusal of a court to receive testimony from a scientist has anything to do with the advancement or progress of science. As the Bayer brief correctly suggests, scientists are constantly formulating and publishing novel theories. Sometimes the theories are supported by substantial data and lead to testable substantial consequences, but often theories are supported only by insubstantial or questionable data or by no data, but only by calculation and speculation[15].

In deciding which expert testimony to admit and which to reject, the court must strike a balance between the risk of rejecting potentially relevant "good science" and admitting "bad science". The problem is that non-scientists, whether judges or jurors, often cannot distinguish between "good science" and "bad science". The expertise provided by the peer review process of experts in a field evaluating proposed theories and

[15]. The case of "string theories" discussed by Penrose, *supra*, is an example of purely theoretical science. The case of "cold fusion" is an example of a theory which is supported only by insubstantial or questionable data and has not been corroborated.

the procedures used to arrive at them is of great assistance in providing judges with a benchmark[16]. By using publication and peer review as a standard, the determination whether particular principles and methodology have received acceptance within the scientific community is one which courts can make. The determination whether particular scientific conclusions are or are not correct or accepted by science is one which judges need not make.

There is superficial appeal to the argument in the Bayer brief that because "truth" in science often changes, the courts should not look to "generally accepted" principles as a standard for admissibility of expert testimony, but the Bayer *amici* are wrong in suggesting that research in the laboratory is the same as presentation of testimony in court. Bayer, *et al.* state some correct fundamental principles and then subtly extend them beyond their realm of applicability. Most important is the notion that in seeking the truth, one must thoroughly examine unorthodox ideas. We agree: in science one must never dismiss a conclusion that is arrived at through sound research techniques simply because it is in disagreement with conclusions that were previously generally accepted. The search for an explanation that reconciles such differences is

[16]. While it is true that there are occasions when "entrenched" peer reviewers attempt to prevent publication of new ideas, we believe that the proliferation of journals and other methods of "publication" makes that rare indeed. A second potential problem occurs when a result or theory is so new that there has not been time for publication and peer review; again the speed of modern communication makes this rare and often occurs when the "scientific" work is done for litigation. In that latter case, the work ought to be somewhat suspect. The occurrence of problems actually resulting from either widespread bias or real novelty is too rare, we submit, to be the proper basis for a general rule of admissibility.

often the spur to scientific inquiry. However, the Bayer *amici* seem to be arguing on this basis that unorthodox results should therefore, *per se*, be acceptable in the courtroom. This is a stretch to absurdity.

It is **how** the conclusions are reached, not **what** the conclusions are, that makes them "good science" today. Conclusions, however divergent from conventional wisdom, that are arrived at by using sound scientific methods, should be considered both in the laboratory and in the courtroom. If, as the Bayer *amici* suggest, the courts have thrown out conclusions because they are not in conformity with conventional thinking, that would be wrong. If courts have thrown out conclusions because the techniques for achieving them were not generally accepted, as the lower courts in this case did, that is a correct course.

In any event, whatever determination a court may make as to the admissibility of proffered scientific testimony in some lawsuit will have no impact at all on the progress or advancement of science. Thus the issue now before the Court does not involve questions of scientific stasis or progress. The issue in the present case is quite simply whether the law should impose liability on the basis of testimony that states a conclusion on a scientific subject that is based on methodology and principles that are not generally accepted by other scientists at the time the testimony is proffered. A court can operate on no other principle, for if it admits conclusions based on methodology and principles that are not now accepted by the scientific community, but **may** in the future come to be accepted, it is operating in the realm of speculation. One

cannot today say what may be accepted 50, 10 or even one year from now. Because litigation must terminate, but science intends to continue inquiring forever, the standards of discourse must be quite different.

As we read the decisions of the lower courts in this case and in other Bendectin cases[17], the federal courts have not excluded experts' conclusions because they are not in conformity with conventional thinking, but generally have correctly refused to admit evidence proffered as scientific when it was based upon methods not generally accepted as scientific.

IV. PETITIONERS' PROPOSED APPROACH IS INADEQUATE AND DANGEROUS

The interpretation of the rules of evidence as they relate to the admissibility of expert testimony in the fields of science advanced by Petitioners is completely inadequate, for it contains none of the safeguards of review, replication and evaluation by the scientific community that are essential parts of the process of acceptable scientific inquiry. It is not enough, we submit, to rely on cross-examination of scientific experts before a lay jury to separate the valid from the bogus. It is doubtful whether a lay jury would understand the intricacies or subtleties

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[17]. *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S.Ct. 1511 (1990); *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3rd Cir. 1990); *Lynch v. Merrell-National Labs*, 830 F.2d 1190 (1st Cir. 1987); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1989), *cert. denied*, 110 S.Ct. 218 (1990); *Turpin v. Merrell Dow Pharmaceuticals*, 736 F.2d 737 (E.D. Ky. 1990), *aff'd*, 959 F.2d 1349 (6th Cir. 1992), *petition for cert. filed*, *Wilson v. Merrell Dow Pharmaceuticals, Inc.*, 893 F.2d 1149 (10th Cir. 1990)

of sophisticated analysis and criticism. Moreover, the credentials of the expert are likely to cause the jury to credit his or her opinion regardless of the validity of the methodology used to arrive at the expert's conclusion.

Petitioners, in essence, would require a court to allow testimony of any individual who possesses adequate formal credentials, regardless of whether the expert's own investigation and analysis conform to scientific norms. It is to the scientific procedural safeguards that a court, this Court, must look to prevent unsupported conclusions -- which may, nevertheless, be appealing to a lay jury -- from being presented as, but are not really, the result of bona fide scientific investigation.

When testimony prepared for litigation is offered through an asserted expert, and the substance of the proffered testimony has never previously been published and tested in the scientific community, the party attempting to challenge such testimony is, in effect, denied the opportunity to show that the methods employed in preparation of such testimony have been widely criticized or rejected by the scientific community, or that the theories employed or the conclusions reached have been rejected or falsified by other scientists. The process of publication and peer review, while not "guaranteeing" the "correctness" of conclusions or opinions advanced by an expert witness provide, at least, some significant assurance that other scientists in the field have had the opportunity to examine and test the expert's methods, data and theories, to consider if they are right or wrong, and to refute them if they are wrong.

This is not an abdication or delegation of the proper role of the court or the jury to editors and staff of scientific journals. Rather, we submit, it is the very procedure that Fed.R.Evid. 703 contemplates when it requires that the facts or data upon which an expert bases his opinion, if not his own, be "of a type reasonably relied on by experts in the particular field in forming opinions or inferences". Petitioners are correct that Rule 703 "is designed to bring judicial practice into line with the practice of experts when not in court." [*see* Advisory Committee Note to Rule 703; *see also* Pet. Br. at 36, n. 65], but are wrong in contending that the decisions of the lower courts are inconsistent with that rule.

CONCLUSION

Publication, peer review and replication are the practices of the scientists outside the courtroom as they proceed with their task of corroborating or falsifying scientific theories and conclusions. This is the method the lower courts insisted on as a prerequisite to admissibility of scientific evidence. The test used by the lower courts in this case is soundly based upon and is in conformity with the requirements of Fed.R.Evid. 703.

For the reasons discussed above, the judgment of the courts below should be affirmed.

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APPENDIX

CREDENTIALS OF *AMICI CURIAE*

NICOLAAS BLOEMBERGEN is a Nobel Laureate in Physics (1981). He is Professor Emeritus at Harvard University. From 1980 to 1990 he was Gerhard Gade University Professor at Harvard University. From 1974 to 1980 he was Rumford Professor of Physics at Harvard University. Professor Bloembergen has also been awarded the National Medal of Science (1974), the Lorentz Medal (1978), the IEEE Medal of Honor (1983), the Frederic Ives Medal (1979), the Oliver E. Buckley Prize for Solid State Physics (1958), the Morris Liebmann Memorial Award given by the Institute of Radio Engineers (1959), the Stuart Ballantine Medal (1961), the Alexander von Humboldt Senior U.S. Scientist Award (1980 and 1987), the Alexander von Humboldt Medal (1989) and the Dirac Medal (1983). He is Commander of the Order of Orange Nassau of The Netherlands (1983).

ERMINIO COSTA, M.D. is Director of the Fidia-Georgetown Institute for Neurosciences. He holds doctoral degrees in medicine and pharmacology. Previously he was Deputy Chief of the Laboratory of Chemical Pharmacology at the National Heart Institute, head of the section of Clinical Pharmacology and Associate Professor of Pharmacology at Columbia University. He is the editor of texts on NEUROPHARMACOLOGY and ADVANCED BIOCHEMICAL PHARMACOLOGY. He is the author of numerous articles.

DUDLEY HERSCHBACH is a Nobel Laureate in Chemistry (1986). He is Baird Professor of Science at Harvard University, where he was previously Professor of Chemistry, Chairman of the Chemistry Department and Chairman of the Chemical Physics program. He is the recipient of the Pure Chemistry Prize of the American Chemical Society (1965), the Linus Pauling Medal (1978), the Michael Polanyi Medal (1981), the Irving Langmuir Prize of the American Physical Society (1983), the National Medal of Science (1991) and the Jaroslav Heyrovsky Medal (1992). Professor Herschbach has published over 300 research papers.

JEROME KARLE is a Nobel Laureate in Chemistry (1985). He is the Chief Scientist of the Laboratory for the Structure of Matter of the Naval Research Laboratory and holds the Chair of Science at the Laboratory. He is the recipient of more than 20 honorary degrees, prizes and awards. He has published approximately 200 articles on theoretical and experimental aspects of the structure of matter. He is a past Chairman of the Chemistry Section of the National Academy of Sciences and Co-President of the Academic Senate of the International Academy of Science. He has been on the editorial board of several scientific journals.

ARTHUR M. LANGER is the Director of the Environmental Sciences Laboratory of the Institute of Applied Sciences and Professor of Geology at Brooklyn College of the City University of New York. He was Associate Professor in the Center for Polypeptide and Membrane Research at the Mt. Sinai School of Medicine in New York and Associate Professor of

Mineralogy at Mt. Sinai. He has been an editor and member of the editorial board of several scientific journals including Environmental Research, American Journal of Industrial Medicine, Journal of Environmental Pathology and Toxicology and Journal of Environmental Pathology, Toxicology and Oncology. He has served on numerous government and international organization committees and consultative groups including the International Agency for Research on Cancer, The United States Food and Drug Administration, the United States Environmental Protection Agency and the National Institute for Occupational Safety and Health. He has published over 60 articles in peer-reviewed journals as well as numerous symposia proceedings, monographs and abstracts.

WASSILY LEONTIEF is a Nobel Laureate in Economics (1973). He is University Professor of Economics at New York University and Director of the Institute for Economic Analysis. He was previously Henry Lee Professor of Political Economy and Professor of Economics at Harvard University and Director of the Harvard Economic Research Project. He has been awarded 13 honorary degrees and numerous prizes and other honors, including an honorary doctorate from the University of Paris (Sorbonne), Karl Marx University, Budapest and the University of Pennsylvania. He is the author or co-author of nine treatises and numerous articles, scientific journals and other periodicals. He is a member and past president of the American Economic Association.

RICHARD S. LINDZEN is Alfred P. Sloan Professor of Meteorology at the Massachusetts Institute of Technology and was previously Burden Professor of Dynamic Meteorology and Director of the Center for Earth and Planetary Physics at Harvard University. He is the recipient of the Macelwane Medal of the American Geophysical Union and of the Meisinger and Charney Awards of the American Meteorological Society. He is a member of the Executive Committee of the National Research Council Space Studies Board, a member of the National Research Council Board on Atmospheric Sciences and Climate, a member of the International Commission on Dynamic Meteorology, and a member of the National Academy of Sciences, the American Geophysical Union and the American Meteorological Society. He is on the editorial board of Pure and Applied Geophysics. He is the author, co-author or co-editor of three monographs and over 160 published papers in the scientific literature.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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BRIEF OF THE AMERICAN MEDICAL ASSOCIATION, AMERICAN MEDICAL ASSOCIATION/SPECIALTY SOCIETY MEDICAL LIABILITY PROJECT,

(Additional *Amici* Listed on Inside Cover)

AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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AMERICAN ACADEMY OF ALLERGY AND IMMUNOLOGY, AMERICAN ACADEMY OF DERMATOLOGY, AMERICAN ACADEMY OF FAMILY PHYSICIANS, AMERICAN ACADEMY OF NEUROLOGY, AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS, AMERICAN ACADEMY OF PAIN MEDICINE, AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN COLLEGE OF PAIN MEDICINE, AMERICAN COLLEGE OF PHYSICIANS, AMERICAN COLLEGE OF RADIOLOGY, AMERICAN SOCIETY OF ANESTHESIOLOGISTS, AMERICAN SOCIETY OF PLASTIC AND RECONSTRUCTIVE SURGEONS, AMERICAN UROLOGICAL ASSOCIATION, AND COLLEGE OF AMERICAN PATHOLOGISTS

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QUESTION PRESENTED

Amici curiae will address the following question:

Whether, under Rule 702 of the Federal Rules of Evidence, a properly qualified expert in a scientific subject must be permitted to testify in federal court, even though the testimony proffered lacks a foundation in established scientific knowledge or is not based upon a valid scientific methodology.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

No. 92-102

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF THE AMERICAN MEDICAL ASSOCIATION, AMERICAN MEDICAL ASSOCIATION/SPECIALTY SOCIETY MEDICAL LIABILITY PROJECT, AMERICAN ACADEMY OF ALLERGY AND IMMUNOLOGY, AMERICAN ACADEMY OF DERMATOLOGY, AMERICAN ACADEMY OF FAMILY PHYSICIANS, AMERICAN ACADEMY OF NEUROLOGY, AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS, AMERICAN ACADEMY OF PAIN MEDICINE, AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN COLLEGE OF PAIN MEDICINE, AMERICAN COLLEGE OF PHYSICIANS, AMERICAN COLLEGE OF RADIOLOGY, AMERICAN SOCIETY OF ANESTHESIOLOGISTS, AMERICAN SOCIETY OF PLASTIC AND RECONSTRUCTIVE SURGEONS, AMERICAN UROLOGICAL ASSOCIATION, AND COLLEGE OF AMERICAN PATHOLOGISTS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

INTEREST OF *AMICI CURIAE*

Amicus American Medical Association (AMA) is a private, voluntary, nonprofit organization of physicians. The AMA was founded in 1846 to promote the science and art of medicine and the improvement of public health. Today its 280,000 members—over half of all physicians currently licensed to practice medicine—practice in all fields of medical specialization.

Amicus American Medical Association/Specialty Society Medical Liability Project (the "Project") was formed in 1986 as a coalition of the American Medical Association, the Council of Medical Specialty Societies, and over 30 national medical specialty societies to present the views of organized medicine on issues related to medical professional liability. The *amici* organizations joining this brief individually are the American Academy of Allergy and Immunology, American Academy of Dermatology, American Academy of Family Physicians, American Academy of Neurology, American Academy of Orthopaedic Surgeons, American Academy of Pain Medicine, American Association of Neurological Surgeons, American College of Obstetricians and Gynecologists, American College of Pain Medicine, American College of Physicians, American College of Radiology, American Society of Anesthesiologists, American Society of Plastic and Reconstructive Surgeons, American Urological Association and the College of American Pathologists.[1]

The issue presented by the holding below is of great importance to the many physicians represented by *amici* and the patients they serve. The issue is of significance to *amici* because standards for professional conduct that are established on a case-by-case basis in the courtroom can have an immediate and lasting impact on medical practices and the price and availability of medical products and services. More broadly, the medical profession

[1] Descriptions of the individual specialty societies that have joined this brief are included in the attached Appendix.

has a stake in preserving and promoting the integrity and legitimacy of medical and other scientific research. In addition, the standards for scientific testimony in the courtroom are of concern to the medical profession because it has an ethical duty to assist in the administration of justice. See AMA, *Current Opinions of the Council on Ethical and Judicial Affairs* § 9.07 (1986). Accordingly, *amici* wish to assist the Court properly to resolve the issue presented.[2]

STATEMENT

Amici adopt the statement of the case as set forth by respondent in its brief in this Court and emphasize the following facts:

Summary judgment was granted to respondent in this case because the district court held that petitioners lacked sufficient evidence that Bendectin caused birth defects. Pet. App. A5. The judgment therefore rested upon the holding that the expert testimony proffered by petitioners lacked a sufficient scientific foundation to be admissible. *Id.* Respondent, by contrast, produced a wealth of scientific evidence that Bendectin, one of the most scientifically tested drugs in history, does not cause birth defects. *Id.* at A2. Over 30 published epidemiological studies have been performed to determine whether Bendectin is a teratogen. None of these studies has ever found any statistically significant correlation between the use of Bendectin and an increase in the incidence of limb defects. *Id.*

The Ninth Circuit held that *in vitro* and *in vivo* animal tests and chemical structure analyses, upon which petitioners' experts sought to base their opinions, did not provide a sufficient scientific foundation for an expert opinion that Bendectin causes birth defects. *Id.* at A3. Moreover, the court of appeals also concluded that peti-

[2] Pursuant to Rule 37.3 of the Rules of this Court, the parties have consented to the filing of this brief. The parties' letters of consent have been filed with the Clerk of the Court.

tioners' experts, in "reanalyzing" existing epidemiological evidence, had simply manipulated the data in existing studies in a scientifically unprincipled way (solely in anticipation of litigation) and had not subjected such "reanalysis" to the scrutiny of other scientists by peer-reviewed publication. *Id.* at A4-A5. Thus, the court below concluded that petitioners lacked any admissible expert evidence on the element of causation and summary judgment was affirmed. *Id.*

SUMMARY OF ARGUMENT

I.

A. Rule 702 of the Federal Rules of Evidence does not permit the admission into evidence of all opinions that are "scientific," in the sense that a scientific issue is the subject of the opinion. See, *e.g.*, *United States* v. *Downing*, 753 F.2d 1224, 1235 (3d Cir. 1985). Rather, pursuant to the language of Rule 702 itself, a scientific expert can only testify to "knowledge" that is "scientific."

B. "Scientific knowledge" is that body of knowledge that has been learned or developed in accordance with rigorous scientific methodology. The scientific method involves replicable, empirical testing of hypotheses. Hypotheses that cannot be corroborated by such testing are discarded. Hypotheses that are repeatedly corroborated are labelled "theories" and generally accepted as valid. Medical knowledge is one kind of scientific knowledge. It is acquired through the application of the scientific method to questions concerning the effects of various interventions on human health.

Medical researchers acquire scientific knowledge through laboratory investigation, studies of animal models, human trials, and epidemiological studies. Such empirical investigations frequently demonstrate *some* correlation between the intervention studied and the

hypothesized result. However, the demonstration of a correlation does not prove the hypothesized result and does not constitute scientific knowledge. In order to determine whether the observed correlation is indicative of a causal relationship, scientists necessarily rely on the concept of "statistical significance." The requirement of statistical reliability, which tends to prove that the relationship is not merely the product of chance, is a fundamental and indispensable component of valid scientific methodology.

C. Judges are capable of distinguishing opinions based upon scientific knowledge from those opinions that are not based upon scientific knowledge, without considering the substance of an expert's opinion. In general, the publication of a study on a particular hypothesis in a peer-reviewed journal indicates that the study is based upon a scientific methodology. Moreover, the complete absence of any peer-reviewed publication supporting a particular hypothesis—particularly one that has been tested numerous times—is powerful evidence that testimony propounding that hypothesis lacks sufficient scientific merit to permit its introduction into evidence.

II.

There is good reason—beyond achieving a just outcome in a particular case—to require testimony of a proffered expert to be based upon scientific knowledge. Recent history demonstrates that legal judgments based upon opinions not developed in accordance with scientific methodology have caused manufacturers to withdraw a number of safe and effective vaccines and drugs, including Bendectin and various contraceptives, from the market. Such legal judgments also have significantly stymied innovation in pharmaceutical and vaccine research. Finally, such judgments have forced certain medical specialists to discontinue providing certain services, particularly

obstetrical care. The withdrawal of beneficial products and medical services has a serious and entirely unwarranted adverse effect on public health. By excluding evidence that is not grounded in the scientific method, Rule 702 promotes the factfinding function of the legal process and simultaneously avoids doing violence to the values that undergird science.

III.

The "reanalysis" of the epidemiological studies at the core of the petitioners' proof of causation was neither published in any peer-reviewed journal nor otherwise developed in accordance with the scientific method. Accordingly, the testimony of petitioners' experts was not based on "scientific knowledge." In light of the overwhelming epidemiological evidence concluding that Bendectin is not teratogenic, testimony based upon such "reanalysis" properly was excluded under Rule 702.

ARGUMENT

I. RULE 702 OF THE FEDERAL RULES OF EVIDENCE EMBODIES A REQUIREMENT THAT EXPERT OPINIONS THAT LACK A LEGITIMATE SCIENTIFIC OR MEDICAL BASIS ARE NOT ADMISSIBLE.

Rule 702 limits expert testimony to "scientific knowledge" that will assist the jury in determining a fact in issue. This does not mean, as petitioners suggest, that any testimony by a qualified expert that relates to a scientific topic and that is relevant to the issues in the case must be admissible in federal court. Rather, expert testimony is based on scientific knowledge, and hence admissible, only when it is based on information derived through the application of the scientific method and not on idiosyncratic theories, calculations or beliefs. The district courts are capable of identifying testimony based on such knowledge, and are obligated by Rule 702 to

exclude all other purportedly scientific testimony. In the medical context, this requires that courts determine that an expert will rely on well-designed clinical or epidemiologic studies, and that they exclude any proffered opinion that lacks such a foundation.

A. Rule 702 Requires That, In Order To Be Admissible, Expert Scientific Opinion Must Be Based In "Scientific Knowledge."

Rule 702 provides that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." Fed. R. Evid. 702. By use of the word "thereto," the Rule makes clear that an expert witness may only testify to "scientific, technical, or other specialized knowledge" that will "assist the trier of fact." At issue in this case is the limitation inherent in the requirement of Rule 702 that admissible expert testimony be based upon "scientific knowledge." [3]

One reason to give the term "scientific knowledge" substantial meaning as a threshold requirement is that expert testimony is accorded special treatment under the Federal Rules of Evidence and existing practice. Experts are "qualified" by the court in the presence of the jury and the jury receives special instructions on the expert's status.[4] Expert witnesses also are exempt from

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[3] Expert testimony may be based upon "technical or other specialized knowledge" as well as "scientific knowledge." "Scientific" experts are professionals recognized as scientific, such as physicians. "Technical" experts may testify to non-scientific man-made rules, such as accounting standards. As the advisory notes suggest, "other specialized" experts include such people as bankers or appraisers who testify about land values. Fed. R. Evid. 702, Advisory Committee's Note.

[4] *See, e.g.*, 1 E. Devitt *et al.*, *Federal Jury Practice and Instructions* § 14.01, at 403 (1992) (jury instructed that expert, unlike

many of the evidentiary restrictions of the Federal Rules: experts need not testify from personal knowledge, they need not testify to the foundation for their opinions, and the bases for their opinion need not be admissible. See Fed. R. Evid. 703, 705. Moreover, experts, unlike other witnesses, generally may testify directly on the "ultimate issues" to be decided by the jury. Fed. R. Evid. 704.

Partially in recognition of the special status of experts, Rule 702 establishes a higher standard for the admissibility of expert testimony, especially testimony by scientific experts, than mere relevance. See, *e.g.*, *United States* v. *Downing*, 753 F.2d 1224, 1235 (3d Cir. 1985) ("we believe that [Rule 702] necessarily implies a quantum of reliability beyond that required to meet a standard of bare logical relevance"); *United States* v. *Williams*, 583 F.2d 1194, 1198-99 (2d Cir. 1978) (similar assessment of factors relating to reliability of scientific evidence), *cert. denied*, 439 U.S. 1117 (1979); see also Fed. R. Evid. 402 ("All relevant evidence is admissible, except as otherwise provided by the Constitution . . . by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority"). Thus, evidence that, according to Ptolemaic methodology, the sun revolves around the earth might be "relevant" (within the meaning of Rule 401) in a particular case, but an otherwise qualified astrophysicist may not so testify because such testimony does not satisfy the requirement that expert testimony be based upon "scientific knowledge." [5]

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other witnesses, is permitted to testify to "opinion" because "such knowledge or experience may be of assistance to you in understanding some of the evidence or in determining a fact"); *see also Manual of Model Criminal Jury Instructions for the District Courts of the Eighth Circuit* § 4.10 (1992); United States Eleventh Circuit District Judges Association, *Pattern Jury Instructions for Civil Cases*, Instruction No. 5.2, at 13 (1990).

[5] The example in the text illustrates the basic principle, but it does not adequately illustrate the problem posed by the evidence in this case. Most jurors probably have formed an opinion concerning the revolution of the earth around the sun, and therefore the admission of testimony to the contrary is not likely adversely to affect the factfinding process. By contrast, whether a drug such as Bendectin causes birth defects is a matter that the ordinary juror will know nothing about. Accordingly, it is only reasonable to ask jurors to make such a scientific judgment when the various scientific hypotheses presented to them have a sufficient basis in scientific method to create a triable dispute.

While the lower courts have universally agreed that expert scientific testimony must satisfy a higher threshold standard than mere relevance, they differ in defining that higher standard of admissibility. One alternative, which most courts have adopted, is the rule in *Frye* v. *United States*, 293 F. 1013 (D.C. Cir. 1923). Under *Frye*, the methodology used by the expert in deriving the opinion must be "generally accepted" by the relevant scientific community. Another alternative, accepted in some form or another by other courts, is to consider various attributes of the expert's methodology and weigh the efficacy of the testimony against the risk of confusing the jury. *Downing*, 753 F.2d at 1237-41; *Williams*, 583 F.2d at 1198-99. The language of Rule 702 itself, however, suggests a somewhat different standard—not only must the opinion be relevant (under Fed. R. Evid. 401), but the opinion must be based (according to Fed. R. Evid. 702) upon "scientific knowledge."

The requirement that an expert opinion must be based in "scientific knowledge" does not simply mean that the subject matter of the testimony must be scientific—*e.g.*, medicine or chemistry or physics. Rather, the limitation imposed by the term "scientific knowledge" requires that the content of the expert's testimony must be developed in accordance with scientific methodology. In particular, the use of the term "knowledge"—rather than "evidence" or "testimony"—underscores the requirement that an expert's testimony be developed in conformance with the rigorous standards of replicable experimentation and re-

porting that are the hallmarks of the scientific method. Only adherence to accepted scientific methodology can produce "knowledge"—*i.e.*, a deduction based upon empirical evidence that can be reproduced, challenged, accepted or built upon by other scientists.[6]

In sum, Rule 702, by its terms and structure, requires that expert testimony satisfy a threshold standard higher than mere relevance.[7] At a minimum, the use of the term "scientific knowledge" should be read to impose a requirement that the content of expert scientific testimony be derived from information developed in accordance with the scientific method. Excluding evidence that does not meet these standards promotes the factfinding function of the legal process and simultaneously avoids doing violence to values of "truth" that undergird science.

B. "Scientific Knowledge" Within The Meaning Of Rule 702 Is Knowledge Derived From The Application Of The Scientific Method.

There is no question that, at any given time, qualified scientists may disagree about the appropriate answer—the most likely answer—to a particular scientific question. Scientific knowledge is not monolithic, and new scientific discoveries and developments are proceeding at a pace that precludes identification of a simple, uniform body of "knowledge." Nevertheless, there is a fundamental and widely accepted distinction between opinions that are based upon scientific knowledge and those that are not: An opinion is only based upon scientific knowledge if it is developed in accordance with the scientific method. Those are the only opinions that Rule 702 permits to be presented to the jury.

1. Scientific knowledge is the body of knowledge that has been developed through application of the scientific method. This method involves empirical testing of a hypothesis. If a hypothesis is contradicted by experimentation (or consistently fails to be corroborated), it is discarded and a new hypothesis must be developed. If a hypothesis is repeatedly corroborated by empirical testing, it is labelled a "theory" and generally accepted as valid. In principle, no scientific theory is ever definitively confirmed because it is always possible that an empirical test will someday demonstrate the theory to be incorrect. As a practical matter, however, some theories are so thoroughly tested that they become virtually incontrovertible. See generally National Academy of Sciences *et al.*, 1 *Responsible Science: Ensuring the Integrity of the Research Process* 36-40 (1992); K. Popper, *The Logic of Scientific Discovery* (1959).

In addition to proceeding from a scientific framework, the development of scientific knowledge requires that testing be conducted, and scientific evidence be developed, in accordance with techniques that science has determined over time to provide reliable and replicable data. Scientific inquiry demands the "pursuit of objective knowledge gleaned from observation." J. Neale & R. Liebert, *Science and Behavior: An Introduction to Methods of Research* 7 (1980). Thus, the validity of any scientific theory depends entirely on a reviewable *empirical* foundation. See J. Monahan & L. Walker, *Social Science in*

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[6] Two experts may, for example, reach the same conclusion about the identity of a person, one using DNA fingerprinting, and the other using alchemy. Only the first expert would be able to testify on the basis of "scientific knowledge." The other would be able to testify only on the basis of speculation and non-scientific belief.

[7] To satisfy Rule 702, expert testimony also must "assist the trier of fact." This requirement of "helpfulness" frequently arises as an issue in criminal cases. In that context, the prosecution often seeks to introduce technologically advanced methods of identification or investigation—such as "DNA fingerprinting"—into evidence. Such methods, while generally based on scientific knowledge, may or may not be sufficiently reliable or accurate to assist the jury. *See, e.g., United States* v. *Jakobetz*, 955 F.2d 786 (2d Cir.) (DNA "fingerprinting"), *cert. denied*, 113 S. Ct. 104 (1992). If a method is not sufficiently accurate, or the predictions a methodology generates are too speculative, then the testimony should be excluded as not helpful to the trier of fact.

Law 33-35 (1985); 1 J. Ziskin, *Coping with Psychiatric and Psychological Testimony* 65 (3d ed. 1981). Absent some accessible (usually published) deduction from a body of empirical evidence, a theory cannot be considered scientific. See Neale & Liebert, at 7, 14 ("The scientific approach requires that all claims be exposed to systematic probes").

Conventional scientific method requires the researcher to identify a means of observing events that permits the hypothesis to be supported or unsupported by the collected data. Hypotheses are framed in terms of the relationship between two variables. For instance, a scientist, in attempting to prove a connection between liver cancer and consumption of coffee, would compare the incidence of liver cancer in a group that did not drink coffee with the incidence in a group that did.

Obviously, there can be numerous causes of liver cancer. Therefore, it will be necessary for the scientist to collect a wide range of empirical data concerning both individuals with liver cancer and individuals without liver cancer and to analyze, using rigorous statistical techniques, the various relationships between the observable characteristics of these individuals and the incidence of liver cancer. The scientist through publication then explains to the scientific community precisely how the data were collected, how the data were analyzed statistically and whether the ultimate hypothesis is supported by the available empirical evidence at a sufficiently high level of confidence to warrant concluding that the relationship between the two variables is not merely the product of chance (or of an independent "confounding" variable, such as heredity). See *Responsible Science*, at 46-64; W.I.B. Beveridge, *The Art of Scientific Investigation* (1957); E. Wilson, Jr., *An Introduction to Scientific Research* (1952).

This methodology develops scientific knowledge by demonstrating that the hypothesized relationship is or is

not supported empirically. If the number of studies reflecting a negative conclusion increases, the confidence in the conclusion increases significantly, causing scientists to discard the hypothesis. G. Friedman, *Primer of Epidemiology* 2-3 (2d ed. 1980). Alternatively, repeated studies also can provide evidence that a relationship between two events does exist.

Finally, scientific method depends significantly upon the peer review process. It requires the scientist to devise methods of data collection that are replicable and to explain precisely how the scientist performed the experiment. Peer reviewers then can analyze the methods and identify potential flaws in the techniques, in the data, or in the statistical methods employed. Research that satisfies the rigors of peer review thus provides assurances that the "knowledge" derived from that research is "scientific." See *Responsible Science*, at 56-59; D. Hull, *Science as Process* (1988).

2. This case specifically involves the application of Rule 702 in the context of medical care. Medical knowledge is the form of scientific knowledge that addresses questions concerning the effects of various interventions on human health. Like other scientists, physicians form hypotheses, test those hypotheses through empirical experimentation, and, based on the results, either discard their hypotheses or build theories. See K. Rothman, *Modern Epidemiology* 7-21 (1986). Medical researchers gather scientific knowledge through laboratory investigations, studies of animal models and, when a particular therapy (*e.g.*, a drug or vaccine) has demonstrated sufficient promise, clinical testing in human subjects. The theories developed through medical testing usually are published in peer-reviewed journals, where they may be studied, questioned or verified by other investigators. A. Relman, *Publishing Biomedical Research: Rules and Responsibilities*, Hastings Center Rep. at 23 (May/June 1990). See *infra*, at 19-21.

The prototypical clinical trial is randomized and "double blind." In such a trial, patients are randomly assigned either to a "treatment" or "control" (placebo) group, and neither the investigator nor the patient knows to which group the patient has been assigned until the experiment has been completed. C. DeAngelis, *An Introduction to Clinical Research* 62-72 (1990).[8] In addition to clinical trials, medical researchers gather scientific information from epidemiological studies, in which they use various statistical methods to determine whether the incidence of a particular disease correlates with other factors. See Friedman, at 2.

As with clinical trials, epidemiological studies generally involve a comparison of a "control" population, which does not feature the variable to be tested, and another group, which does. For example, in this case, the relevant studies concerning the relationship between the use of Bendectin by pregnant women and limb defects in children compared the incidence of birth defects in women who took Bendectin and in women who did not. See J. Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L.J. 301 (1992) (describing Bendectin studies).

Medical studies, whether clinical trials or epidemiologic studies, frequently demonstrate *some* correlation between the action studied (*e.g.*, the ingestion of a drug) and the hypothesized result (*e.g.*, a decrease in the size of a tumor). To determine whether the observed correlation is not due to chance, medical scientists rely on the concept of "statistical significance." A "statistically significant" correlation is generally considered to be one in which statistical analysis suggests that the observed relationship is not the result of chance. A statistically signifi-

[8] *See also* C. Oyster *et al., Introduction to Research: A Guide for the Health Science Professional* 55-65 (1987); C. Meinert & S. Tonascia, *Clinical Trials: Design, Conduct, and Analysis* 65-70 (1986).

cant correlation does not "prove" causation, but in the absence of such a correlation, scientific causation clearly is not proven.[9] See generally S. Selvin, *Statistical Analysis of Epidemiologic Data* 17-20 (1991).

Rule 702, by incorporating the term "scientific knowledge," is most naturally read to embrace this common understanding of what that term means. Accordingly, the Rule seems plainly to require district courts to make an initial judgment concerning the nature of the knowledge underlying a particular expert's testimony. Although that initial scrutiny is vital to the proper application of Rule 702, it should not impose a significant burden on the district courts.

C. Courts Are Capable Of Distinguishing Opinions Based Upon Valid Scientific Knowledge And Methodology From Opinions That Lack A Scientific Basis And Must Exclude The Latter From Evidence.

This Court's announcement of a rule interpreting Rule 702 to limit expert testimony on "scientific" matters to those opinions and facts based upon scientific knowledge would not impose an unworkable burden on litigants or

[9] It is misleading to compare the 95% confidence level used in empirical research to the 51% level inherent in the preponderance of the evidence standard. *See generally* D.H. Kaye, *Apples and Oranges: Confidence Coefficients and the Burden of Persuasion*, 73 Cornell L. Rev. 54-77 (1987). The distinction lies in the difference between statistical association and legal causation (proximate cause). A plaintiff need only demonstrate by a preponderance of evidence that a product was the proximate cause of his or her particular injury. He or she must, however, demonstrate with a much higher degree of certainty that there is a statistical association between use of the product and the type of injury that he or she suffered. Thus, the courts correctly have recognized that scientific studies should be statistically significant before being allowed into evidence. *See Ealy* v. *Richardson-Merrell, Inc.*, 897 F.2d 1159, 1161-62 (D.C. Cir. 1990); *see generally Marder* v. *G.D. Searle & Co.*, 630 F. Supp. 1087, 1092 (D. Md. 1986), *aff'd without op.*, 814 F.2d 655 (4th Cir. 1987); *In re Agent Orange*, 597 F. Supp. 740, 785 (E.D.N.Y. 1984).

upon the district courts. Although most judges are not scientists, judges are fully capable of distinguishing expert testimony that is based upon "scientific knowledge" from expert testimony that is not. In some cases, this may simply require the courts to identify a universally accepted theory as the basis of the testimony. In other cases, where a legitimate scientific debate exists, the proposed rules would require the trial judge to determine whether the proffered testimony has a foundation in scientific knowledge—*i.e.*, a scientific methodology.

On some issues, a scientific or medical theory is essentially beyond dispute because the theory has been corroborated by testing so many times that scientists have a very high confidence in its validity. For example, scientists are universally satisfied that the earth revolves around the sun, not vice versa. Views such as the plainly constitute "scientific knowledge," and can easily be recognized by the courts. Where an expert opinion rests upon a generally accepted scientific theory, the testimony should be admissible.

In other cases, however, the disputed issue cannot be explained by any single generally accepted scientific theory. Instead, both sides will offer to explain the disputed fact by means of conflicting expert testimony. In such cases, a trial judge can still determine whether the opinion proffered by a scientific expert is truly the product of scientific knowledge. To do so, the trial court must determine only whether the expert relied upon the scientific method in reaching his or her opinion. The court need not, at any time, consider the substance or conclusion of the expert's opinion. Indeed, two competing expert opinions in a given case can both be "scientific," and the court in that case need not decide which is correct. It need only determine whether both approaches are the product of a proper scientific methodology.[10]

[10] The adversary process of the law will never be a perfect vehicle for resolving scientific disputes. Neither judges nor juries are particularly well suited to deciding differences of scientific opinion. However, the problems inherent in the capacity of the judicial process to resolve such disputes will only be exacerbated if the rules do not provide some threshold check on what expert opinions are admissible.

To determine whether testimony is the product of scientific methodology, courts should require an expert to explain his or her methods so that it can assess them in light of Rule 702. In some cases, a pretrial hearing (see Fed. R. Evid. 104(a) and (b)) or voir dire may be required. The Rules also permit the court to appoint its own expert, who can assess whether proffered testimony constitutes "scientific knowledge." Fed. R. Evid. 706. In addition, the courts can and should look to whether the facts supporting the evidence have been published in peer-reviewed journals. The mere fact that research has not been subjected to peer review does not render unscientific that which otherwise conforms to scientific standards. Nonetheless, peer review usually assures that knowledgeable experts in the field have already read a paper with critical eyes, and thus it can play an important role in the court's Rule 702 determination.

Peer review cannot assure the ultimate validity of an article's conclusions. Reviewers may not, for example, detect fraud or carelessness in data or other sorts of errors that are not readily apparent. Peer review, however, is a significant indicator that an article is "scientific," because reviewers are well-positioned to identify conceptual departures from the scientific method. "Good peer reviewed scientific journals should provide their readers with reports of the best available research, free of obvious major flaws." A. Relman & M. Angell, *How Good Is Peer Review?*, 321 New Eng. J. Med. 827, 828 (1989).

Moreover, it is implicit within the scientific method's requirement of reproducibility that results will in fact be reproduced and confirmed by other scientists.

Peer review and publication further that process, which makes it more likely that fraud or other shortcomings will be detected. See D. Hull, *Science as Process* (1988); J. Ziman, *Reliable Knowledge* (1978). Thus, publication in a peer-reviewed journal should constitute significant evidence that the research adhered to "scientific" standards, as Rule 702 requires. The absence of peer review, particularly in circumstances in which the theory is novel or contrary to the weight of the scientific research, is a strong indication that the testimony lacks a scientific foundation.

In sum, district courts can determine whether proffered expert testimony is sufficiently grounded in scientific knowledge to warrant its admission into evidence under Rule 702. To do so, they must determine whether the testimony relies on information derived through application of the scientific method. In general, this requires that they determine that the testimony is based on rigorously controlled, reproducible scientific studies. In the medical context, they must determine that the expert will rely on well-designed clinical or epidemiologic studies. Publication of information in a peer-reviewed journal is a strong indication that that information reflects "scientific knowledge," whereas the absence of publication is indication to the contrary. Where, as here, there has been ample opportunity for publication, the conclusion is inescapable that expert testimony relying on information that has not been peer-reviewed has no basis in "scientific knowledge."

II. THE ADMISSION OF "EXPERT" OPINIONS THAT DO NOT HAVE A BASIS IN SCIENTIFIC KNOWLEDGE HAS AN ADVERSE EFFECT ON MEDICAL PROFESSIONALS, THEIR PATIENTS, AND SOCIETY.

In addition to the plain language of Rule 702, sound public policy counsels that expert testimony should be limited to opinions based upon scientific knowledge. Obviously, the introduction of evidence not grounded in scientific knowledge may lead to inequitable judgments in individual cases. *Cf.* Fed. R. Evid. 102 (the Federal Rules of Evidence should be construed to further the goal of ascertaining the truth and providing a just determination of a case). But, more fundamentally, permitting civil damage actions to be decided on the basis of opinions not grounded in scientific knowledge will, over time, have a detrimental effect on the medical profession and the patients it serves.[11]

Indeed, examples from recent history demonstrate that as a result of legal judgments based upon invalid medical or scientific opinions, medical professionals have been deprived of a number of valuable tools. "Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance." AMA Board of Trustees, "Impact of Product Liability on the Development of New Medical Technologies" ("AMA Report"), at 1 (June 1988). In addition, medical professionals have themselves been compelled to modify their practices or to stop providing certain services because of the threat of liability imposed by such judgments. By forcing these valuable products and services off the market, legal judgments not grounded in science ultimately have an adverse effect

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[11] There is no question that standards of tort liability are intended to have, and do have, an effect on behavior. *See* D. Hughes *et al., Obstetrical Care for Low-Income Women*, in II *Medical Professional Liability and the Delivery of Obstetrical Care* 59, 73-74 (V. Rostow & R. Bulger eds., 1989); A. Relman, *Medical Professional Liability and the Relations Between Doctors and Their Patients*, in II *Medical Professional Liability*, at 97, 99-103; P. Bell, *Legislative Intrusions into the Common Law of Medical Malpractice: Thoughts about the Deterrent Effect of Tort Liability*, 35 Syracuse L. Rev. 939, 971 (1984); see also *Browning-Ferris Indus. Inc.* v. *Kelco Disposal, Inc.*, 492 U.S. 257, 282 (1989) (O'Connor, J., concurring) ("The threat of . . . [unfounded punitive damage] awards has a detrimental effect on the research and development of new products").

on the health of patients. See, *e.g.*, D. Hughes *et al.*, *Obstetrical Care for Low-Income Women*, in II *Medical Professional Liability and the Delivery of Obstetrical Care* 59, 73-74 (V. Rostow & R. Bulger eds., 1989).

Bendectin itself is a prime example of a beneficial drug, which has been approved as "safe and effective" by the Food and Drug Administration,[12] but which is no longer available to physicians and patients because of liability imposed on the basis of unscientific expert testimony. More than 30 scientific studies have been conducted to determine whether any statistically significant correlation exists between the use of this drug and limb defects. No study has demonstrated such a correlation. See J. Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L.J. 301 (1992) (summarizing the findings).

Nevertheless, women suffering from morning sickness cannot purchase Bendectin (or any other treatment)—despite the fact that severe morning sickness can have significantly adverse medical side-effects. Nausea and

[12] The FDA conducts extensive pre-approval testing, in three "phases," on every new drug. Phase I principally involves testing for toxic side-effects on approximately 20 to 80 subjects. Phases II and III consist of "controlled clinical studies" on hundreds or even thousands of human subjects. 21 C.F.R. § 312.21. These clinical trials must be "well-controlled" and have enough subjects so that they are "scientifically valid." *Id.*

The FDA determined Bendectin to be "safe" in 1956. Because of public concerns about the safety of the drug, the FDA's Fertility and Maternal Health Drugs Advisory Committee—an independent expert panel composed of physicians, scientists and a consumer representative, and advised by scientists from the National Institutes of Health—reviewed this determination in 1980. Following public hearings and an extensive review of the evidence, this committee concluded that there is no increased incidence of birth defects resulting from exposure to Bendectin. The FDA announced its agreement with this finding, and the agency has stood by it ever since. *See Richardson* v. *Richardson-Merrell, Inc.*, 649 F. Supp. 799, 803 (D.D.C. 1986), *aff'd*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989).

vomiting can cause dehydration and acidosis, which can, if untreated, result in nutritional deficiencies, nerve damage, birth defects, and—in the worst cases—can threaten the life of the pregnant woman and her fetus. In short, the inability to obtain Bendectin has left a "significant therapeutic gap" in the treatment of morning sickness. See AMA Report, at 11.

The adverse impact of unfounded liability also has been keenly felt by manufacturers of contraceptives. Indeed, a recent study by the National Research Council and the Institute of Medicine concluded that product liability concerns "have contributed significantly to the climate of disincentives for the development of contraceptive products." National Research Council & Institute of Medicine, *Developing New Contraceptives—Obstacles and Opportunities* 141 (L. Mastroianni *et al.* eds., 1990). The study emphasized in particular the "unpredictable nature of litigation." *Id.*

The AMA also has documented the dramatic drop in basic research in this area:

> In the early 1970s, there were 13 pharmaceutical companies actively pursuing research in contraception and fertility. Now, only one US company conducts contraceptive and fertility research. Unless the liability laws are drastically altered, it is very unlikely that pharmaceutical companies will aggressively pursue research in this area.

AMA Report at 9.

The Copper-7 intrauterine device ("IUD") provides a striking case study of the effect of liability concerns on the availability of vaginal contraceptives. Use of this IUD involves a very slight risk of pelvic inflammatory disease. However, most physicians endorse the use of the product in appropriate patients, and the FDA still considers it to be "safe and effective." A number of federal courts, however, have allowed experts to offer opinions

without basis in scientific methodology suggesting that this IUD is far more dangerous than any legitimate study has demonstrated. See, *e.g.*, *Amore* v. *G.D. Searle & Co.*, 748 F. Supp. 845 (S.D. Fla. 1990). As a result, although the manufacturer prevailed in a number of cases alleging injury based upon the use of this IUD, see *id.* at 848 n.3, by 1986, it became impossible to purchase insurance for the product. Such a result is plainly contrary to the public interest—particularly, in light of established knowledge that IUD's are, in fact, the most effective and safest contraceptive option for some women, especially older women. See H. Cole ed., *Diagnostic and Therapeutic Technology Assessment (DATTA): Intrauterine Devices*, 261 JAMA 2127 (1989).

The admission of unscientific testimony also has affected the availability of many vaccines. Vaccines, particularly those for childhood diseases, "are one of the greatest success stories of medicine." AMA Report, at 6. Most domestic manufacturers, however, have stopped producing and distributing childhood vaccines. *Id.* More than half of the vaccine producers licensed in 1968 have ceased production, and this country is now "heavily dependent on sole suppliers" for many pediatric vaccines. Institute of Medicine, *Vaccine Supply and Innovation* ("*Vaccine Supply*") 5 (1985). The primary cause of this precipitous decline in vaccine production capacity has been "the liability situation and its consequences (*i.e.*, litigation costs or difficulty in obtaining insurance coverage)." *Id.* at 11.[13]

Here again, an example is illustrative. Thorough epidemiological studies have demonstrated that there is

[13] In some cases, Congress has been forced to adopt no-fault compensation systems in an effort to keep good vaccines available. *See* W. Mariner, *The National Vaccine Injury Compensation Program*, Health Affairs, Spring 1992, at 255, 259 ("[the program] was created to avoid disputes about whether a vaccine caused adverse reactions at all").

no statistically significant relationship between the vaccine for diphtheria, tetanus, and pertussis (whooping cough) and encephalopathy, an inflammatory brain disease. See M. Griffin *et al.*, *Risk of Seizures and Encephalopathy After Immunization With the Diphtheria-Tetanus-Pertussis Vaccine*, 263 JAMA 1641 (1990). Nonetheless, all but one manufacturer stopped making this vaccine following a series of lawsuits based upon unsubstantiated medical "opinion" that the pertussis portion of the vaccine might in fact be causing encephalopathy. See J. Cherry, *"Pertussis Vaccine Encephalopathy": It Is Time to Recognize It as the Myth That It Is*, 263 JAMA 1679 (1990); *Vaccine Supply*, at 27, 68.[14] As a result, the medical profession almost lost one of its most successful and widely used childhood vaccines.

In addition to threatening the supply of existing vaccines, the prospect of medically unfounded tort liability is retarding innovation. See, *e.g.*, FDA, "Biological Products: Bacterial Vaccines and Toxoids: Implementation of Efficacy Review," 50 Fed. Reg. 51002, 51006 (Dec. 13, 1985) ("attempts to improve vaccines further will be hampered" by tort liability); *Vaccine Supply*, at 11 ("apprehensions [concerning liability] are a disincentive to investment in the development of new (or improved) immunizing agents").[15] The prospect of undue

[14] One such suit was *Graham* v. *Wyeth Laboratories*, 906 F.2d 1399 (10th Cir.), *cert. denied*, 111 S. Ct. 511 (1990). In *Graham*, the plaintiff's experts testified that the "endotoxin content" of the vaccine was much higher than other vaccines on the market. As it turned out, the plaintiff's experts had grossly miscalculated the endotoxin content, which was ten times less than their estimate. The defendant, on the other hand, produced well-grounded medical evidence that the plaintiff's injuries actually were caused by a stroke weeks before the vaccine was administered. *Id.* at 1407-11 (reversing $15 million judgment against manufacturer).

[15] *See also Vaccine Injury Compensation: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong., 2d Sess. 115 (1986) (statement

liability also may be holding back the development of a vaccine for the AIDS virus. See J. Cohen, *Is Liability Slowing AIDS Vaccines?*, 256 Science 168 (Apr. 10, 1992).

Finally, unscientific judgments also have adversely affected the provision of medical services.[16] When unscientific testimony is introduced into evidence, it changes the deterrent signal of the tort system in a way that communicates to physicians that following sound medical practice will not protect them from liability. In particular, many obstetricians have been subject to successful tort claims attributing various ailments, including cerebral palsy, to their improper handling of deliveries and their failure to perform cesarean sections. See, *e.g.*, *Low* v. *United States*, 795 F.2d 466 (5th Cir. 1986); *Nemmers* v. *United States*, 612 F. Supp. 928 (C.D. Ill. 1985), *vacated on other grounds*, 795 F.2d 628 (7th Cir. 1986); see also N. Rhoden, *The Judge in the Delivery Room: The Emergence of Court-Ordered Cesareans*, 74 Cal. L. Rev. 1951, 2010-23 (1986). As a result of such claims, malpractice premiums for obstetricians and family physicians who practice obstetrics have skyrocketed, driving many such physicians out of that practice, especially in rural areas. See American College of Obstetricians and Gynecologists, *Professional Liability Insurance and Its*

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of Dr. Martin H. Smith, President, American Academy of Pediatrics) ("research efforts for new and improved vaccines have been chilled" because of liability concerns).

[16] Fear of uncertain liability also causes physicians to practice "defensive medicine"—*i.e.*, the provision of additional tests, procedures, services and recordkeeping that are justified more by the need to defend clinical decisions in the microscopic hindsight of malpractice litigation than by a wholly objective assessment of the patient's diagnostic or therapeutic needs. As long as the law allows theories of liability to be supported by unscientific opinion in the guise of expert testimony, the deterrent effect of tort liability is distorted causing physicians to practice defensive medicine, with the inevitable increase in health care costs.

Effects; Report of a Survey of ACOG's Membership (1992).

The available scientific evidence, however, provides no support for the hypothesis that cerebral palsy results from improper delivery techniques. Indeed, it is increasingly clear that obstetricians have virtually no ability to prevent cerebral palsy through either the use of electronic fetal monitoring devices or more frequent cesarean sections. See K. Shy *et al.*, *Effects of Electronic Fetal-Heart-Rate Monitoring, as Compared with Periodic Auscultation, on the Neurologic Development of Premature Infants*, 322 New Eng. J. Med. 588 (1990). In fact, the medical consensus is that too many cesarean sections are now performed in the United States. See S. Myers & N. Gleicher, *A Successful Program to Lower Cesarean-Section Rates*, 319 New Eng. J. Med. 1511 (1988).

In short, the admission of unscientific medical "opinion" furthers no legitimate scientific, legal or social purpose. To the contrary, if opinions that lack a scientific foundation are admitted into evidence, then some judgments inevitably will be based on those opinions. And, as a result, the practice of medicine will be influenced by these judgments, to the detriment of the health of the public. Such a perverse result is at odds with the goals of the Federal Rules of Evidence and of the judicial process itself, and makes the law the enemy of good science.

To be sure, the law will always remain something of a mystery to professionals in other disciplines, just as the nuances of science will lie beyond the competence of most attorneys. But the law loses credibility in the eyes of physicians and other scientists when it imposes liability, or even the risk of liability and the burdens of trial, on the basis of evidence that lacks serious scientific merit. Those trained in science and medicine quite rightly have little respect for the workings of the law if it does nothing more than transfer resources from one party to an-

other without regard to the basic methodologies and common understanding of scientific practitioners.

In particular, liability imposed on physicians on the basis of unscientific testimony will cause some practitioners to stop providing services that, while medically indicated, involve a high risk of suit. Similarly, it will cause practitioners to seek "diagnostic certainty" and provide excessive services, thereby adding unnecessary billions of dollars to the cost of medical care. Rule 702 does not require such harmful consequences. To the contrary, the Rule's language and structure evince an intent to promote the truth-finding process both inside and outside the courtroom by requiring expert opinion to be based on scientifically accepted methods.

III. THE NINTH CIRCUIT CORRECTLY EXCLUDED THE TESTIMONY PROFFERED BY PETITIONERS' EXPERTS IN THIS CASE.

More than 30 rigorous, controlled, and reviewed studies have been conducted to determine whether there is a statistically significant correlation between the use of Bendectin and an increase in the incidence of birth defects. None of these studies found any such correlation. Thus, they tend strongly to disprove the hypothesis that Bendectin causes birth defects. Because these studies were performed according to the standards of science, their conclusions contribute to medical knowledge. These studies therefore are admissible under Rule 702.

On the other hand, not one peer-reviewed study has been published that demonstrates the existence of any statistically significant association between Bendectin and limb defects. Given the significant attention that the scientific community has paid to this issue, the absence of any such published findings strongly supports the court of appeals' conclusion that the opinions offered by petitioners' experts simply lack sufficient scientific bases to permit the introduction of those opinions into evidence,

The "reanalysis" of the epidemiological studies proffered by petitioners' experts in this case did not conform to the standards of the scientific method.[17] As the district court stated, Dr. Adrian Gross recalculated the data in existing epidemiological studies. He did not publish his calculations or subject them to the scrutiny of other scientists through the process of peer review. "Nowhere does [Dr. Gross's study] state that Bendectin sales increased the relative risks of limb reduction defects to a level significantly above 1.0 with a confidence interval that did not include unity." JA 236. In other words, even Dr. Gross did not find a statistically significant difference. The same is true of all of petitioners' remaining experts. JA 232-36. The opinions of these experts therefore were not based upon "scientific knowledge." Therefore, the court of appeals properly upheld the district court's exclusion of their testimony.

* * * *

The touchstone of Rule 702 is scientific knowledge. Under this Rule, expert scientific testimony must adhere to the recognized standards of good scientific methodology including rigorous analysis, accurate and statistically significant measurement, and reproducibility. One helpful, but not dispositive, indication that knowledge has a scientific basis is the existence of published, peer-reviewed

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[17] "Reanalysis" or "meta-analysis" of existing epidemiological data—when properly conducted and reviewed—may be an acceptable scientific methodology. *See* H. Kahn & C. Sempos, *Statistical Methods in Epidemiology* 8-11 (1989); O. Miettinen, *Theoretical Epidemiology* 109-15 (1985); T. Colton, *Statistics in Medicine* 99-146 (1974). Indeed, a "meta-analysis" may find statistical significance across a range of studies where no individual study found a statistically significant result. *See* H. Sacks *et al.*, *Meta-Analyses of Randomized Control Trials*, in *Medical Uses of Statistics* 427-41 (J. Bailar & F. Mosteller eds., 2d ed. 1992). However, there is no indication that a statistically valid meta-analysis—*i.e.*, a meta-analysis performed in accordance with scientific methodology—was performed by any of the expert witnesses proffered by petitioners.

studies supporting it. When expert testimony is not based on peer-viewed studies and is not otherwise based upon information acquired through the scientific method is admitted into evidence, there is a risk that judgments will be based on such testimony and that scientific professionals will alter their behavior accordingly. As applied to the medical profession, deviations from science ultimately have an adverse effect on public health, as this case well illustrates. The Federal Rules of Evidence were never intended to, and should not be interpreted to, place the rules of law and science at odds with one another.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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January 19, 1993

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APPENDIX

The American Academy of Allergy and Immunology was organized as a nonprofit society in 1943 and has since become the largest national professional medical society in the field of allergy, clinical immunology and related diseases. It represents 4,600 physicians and allied health professionals in the United States, Canada, and 41 foreign countries. Its purposes are to advance the practice of immunology, to foster the education of both students and the public, and to promote cooperation among those engaged in the fields of allergy and immunology.

The American Academy of Dermatology is the largest professional association of physicians specializing in dermatology. Its primary goals are to promote and advance the science and art of medicine and surgery related to the skin, hair, nails and mucous membranes and promote the highest possible standards in clinical practice, education and research in dermatology and related disciplines.

The American Academy of Family Physicians is a private, voluntary, non-profit organization of physicians, with a membership of more than 74,000 family physicians and medical students. Included among the Academy's objects and purposes are to preserve and promote quality cost-effective health care and to provide responsible advocacy for and education of patients and the public in all health-related matters.

The American Academy of Orthopaedic Surgeons is the primary educational and professional organization of orthopaedic surgeons in the United States. Founded in 1933, the Academy is an Illinois not-for-profit corporation whose Fellowship includes nearly 18,500 orthopaedic surgeons, approximately 96% of the board-certified orthopaedic surgeons in the United States.

The American Academy of Pain Medicine is a not-for-profit organization with over 600 physician members. The

Academy is dedicated to pursuing excellence in education as it concerns Pain Medicine and related sciences, and to upholding high principles, policies and practices for the attainment of the best in care for the patient suffering with pain.

The American Academy of Neurology is a nonprofit organization of over 11,000 neurologists and neuroscientists throughout the United States and abroad, and is the only medical organization that speaks for all of neurology. Neurologists are committed to the treatment and research leading to cures for disorders of the nervous system—the brain, spinal cord and nerves. The Academy is equally committed to fostering the educational and professional advancement of its members and supports efforts to ensure that the integrity of this profession is maintained.

The American Association of Neurological Surgeons is a private, voluntary non-profit organization of neurosurgeons. The Association was founded in 1931 as The Harvey Cushing Society to: (1) promote optimum quality in the delivery of neurosurgical care, while maintaining cost-effectiveness; (2) provide relevant and significant education programs for the neurosurgical community; (3) promote research in the neurosciences. Today, its membership of nearly 3,800 includes Board-certified neurosurgeons, as well as individuals who have shown distinction in many related medical disciplines.

The American College of Obstetricians and Gynecologists is a private, voluntary, non-profit organization of physicians who specialize in obstetric and gynecologic care. The College is the leading group of professionals providing health care to women; its 32,000 members represent approximately ninety percent of all obstetricians and gynecologists practicing in the United States. Obstetricians and gynecologists are the most frequently sued of all the speicalities, with approximately 80% of the College's members having experienced at least one medical liability suit. For such a high-risk specialty, it is especially important that medical expert testimony used in litigation be scientifically valid.

The American College of Pain Medicine was formed in 1991 as an educational not-for-profit corporation. Its purpose is to act as an educational association of physicians (Doctors of Medicine, Doctors of Osteopathy), to conduct examinations and to award Fellowship certification in the medical specialty of pain medicine.

The American College of Physicians is a private, voluntary, nonprofit organization of physicians trained in internal medicine, and diagnosis and nonsurgical treatment of disease and illness in adults and young adults. The College is the nation's largest medical specialty society, with more than 77,000 members who include practitioners providing primary care; medical specialists in fields such as cardiology, neurology, and oncology; and medical researchers and educators. Founded in 1915 to uphold high standards in medical practice, education, and research, the College continues to strive to meet those goals and has more recently added practice standard-setting; technology assessment; and health policy, ethical, and medical-legal issues analysis to its activities.

The American College of Radiology, which was founded in 1923, is the principal organization of radiologists in the United States, with more than 28,000 members. The College is a non-profit membership association whose principal purposes are to advance the science of radiology, improve services to the patient, and encourage continuing education for radiologists and persons practicing in allied professional fields.

The American Society of Anesthesiologists is a voluntary not-for-profit New York corporation. The Society has an active membership of over 20,000 physicians or other scientists practicing or especially interested in the specialty medical practice of anesthesiology.

The American Society of Plastic and Reconstructive Surgeons is a private, voluntary, non-profit organization

of board-certified plastic surgeons founded in 1931. The mission of the Society is to promote optimal care for plastic surgery patients through education, research and high professional standards, and to support its members' socioeconomic and professional activities. The Society represents approximately 5,000 board-certified plastic surgeons in the United States and Canada.

The American Urological Association is a private, voluntary, non-profit organization of urologists. The Association was founded in 1902 to be the professional organization which fosters the highest standards of urologic care through education, research and the representation of the membership in formulation of health care policy. The current membership is 8,830 urologists around the world.

The College of American Pathologists is a national medical specialty society serving more than 13,000 members and the laboratory community. The College offers member services, quality assurance programs, and management resources designed to enhance pathology practice for its members and to improve laboratory services for physicians and the public.

[redacted]

[redacted]

[redacted]

QUESTION PRESENTED

Amicus will address the following issue:

Whether, consistent with the principles of federalism articulated in *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938), Congress or the federal courts may impose, in cases arising under the federal courts' diversity jurisdiction, a rule of evidence governing the admissibility of expert testimony that may be at variance with a forum state law.

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IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1992

No. 92-102

WILLIAM DAUBERT and JOYCE DAUBERT,
Individually and As Guardians Ad Litem for
JASON DAUBERT, and ANITA DE YOUNG, Individually
And As Guardian Ad Litem for ERIC SCHULLER,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

On Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

INTEREST OF THE *AMICUS*

The Washington Legal Foundation ("WLF") is a national nonprofit public interest law and policy center with more than 100,000 members throughout the United States. WLF seeks to promote and protect the free enterprise system and the economic and civil liberties of individuals and businesses. WLF has long been interested in the promotion of tort reform to ensure that the free-enterprise system is preserved.

To that end, WLF has appeared as *amicus curiae* before this Court as well as other state and federal courts to urge the adoption of procedural rules that will minimize the likelihood that unwarranted tort liability will be assessed on the business community. *See, e.g., Burlington Northern Railroad Co. v. Ford*, 112 S. Ct. 2184 (1992); *Pacific Mutual Life Ins. Co. v. Haslip*, 111 S. Ct. 1032 (1991). WLF believes that the public interest is best served by a legal system that does not subvert the courts' truth-finding processes in a rush to provide compensation to all who have suffered injuries.

This brief will bring relevant authorities to the attention of the Court which may not be brought to the attention of the Court by the parties or by other *amici curiae*. Among other things, this brief will demonstrate that Congress and the federal courts may protect the integrity of the federal courts' truth-finding process by employing an evidentiary rule which excludes incompetent expert scientific testimony in civil diversity cases that would unduly prejudice or confuse a jury.[1] Such a rule does not violate principles of federalism because it is consistent with the power given the federal courts under Article III of the Constitution and does not infringe on any state's substantive policy or on any rights or obligations guaranteed by the states. *Amicus* has no other interest in the resolution of this case, political or economic.

WLF submits this brief in support of Respondent with the written consent of both parties. The written consents are on file with the Clerk of the Court.

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[1] Respondent convincingly demonstrates that the Federal Rules of Evidence incorporate the rule in *United States v. Frye*, 293 F.2d 1013 (D.C. Cir. 1923), which excludes incompetent so-called scientific evidence. This brief demonstrates that this exclusionary rule does not offend principles of federalism.

STATEMENT

In the interest of brevity, WLF adopts the Statement included in Respondent's brief.

SUMMARY OF ARGUMENT

The Ninth Circuit has followed the First, Fifth and District of Columbia Circuits and required that expert scientific testimony be based on "generally accepted" scientific principles to be admitted into evidence under Article VII of the Federal Rules of Evidence. This requirement, first enunciated in *United States v. Frye*, 293 F. 1013, 1014 (D.C. Cir. 1923), is intended to protect the integrity of the truth-finding process by excluding evidence that would unduly prejudice or mislead the jury or confuse the issues. This rule applies to all civil actions, and does not favor any class of people over any other, or impair the substantive policy of any state. Petitioners contend that the Ninth Circuit's adherence to this exclusionary rule violates the principles of federalism first articulated by this Court in *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938), because it is "outcome determinative" and impairs substantive rights guaranteed by the states. (Petitioners' Brief at 41.) This argument is fundamentally unsound.

Rules of evidence may be "outcome-determinative" in the sense that they assist the fact-finder to find the truth based on facts and not on conjecture, surmise, or emotional appeal. However, this effect in no way contravenes *Erie* principles. Indeed, to suggest that *Erie* and its progeny exclude all court rules that are "outcome determinative" would be to abrogate the Federal Rules of Evidence in diversity cases. *Erie* principles require no such result.

The federal government has a legitimate interest in ensuring that the federal judiciary operates as an independent and effective judicial system. Consistent with

this interest, the Constitution allows Congress and the federal courts to adopt their own rules of procedure in diversity actions as long as those rules do not impair substantive state policies. Necessarily, the interest of an independent and effective federal judiciary may conflict with federalism's interest in uniformity of outcome. This Court, since its decision in *Byrd v. Blue Ridge Rural Electric Coop.*, 356 U.S. 525 (1958), has resolved such conflicts by examining the policies behind the federal and state interests. It is only where the federal rule significantly impinges upon a state substantive policy that the federal procedural rule must yield -- even in the case of a judge-made rule.

Rules that assist the truth-finding process by excluding prejudicial or confusing evidence do not impinge on any important state substantive interest. If anything, federal and state interests are identical: to find the truth in the most fair and efficient manner possible. Isolated differences in outcome, derived from variations in approach, to ensure the existence of an independent federal judiciary, are not prohibited by *Erie*. The fact that state courts may approach the truth-finding process in slightly different ways from the federal courts in a given instance does not create a state-guaranteed right. *Byrd* allows the federal courts to follow the truth-seeking rules Congress or the federal court determine to be the best suited for this purpose. This Court has never required just results to give way in favor of uniform outcomes.

The judgment of the United States Court of Appeals for the Ninth Circuit should be affirmed.

ARGUMENT

I. THE *FRYE* RULE IS A "TRUTH FINDING" RULE THAT DOES NOT IMPAIR THE SUBSTANTIVE LAW OF THE STATES

In the opinion below, the Ninth Circuit held that expert scientific testimony must be based on a methodology "generally accepted as a reliable technique among the scientific community." (Jt. App. at 238 (quoting *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985).) Petitioners' arguments notwithstanding, this rule, or indeed any other rule limiting the admissibility of expert testimony, does not violate the principles of federalism first articulated in *Erie Railroad Co. v. Tompkins*. This is true whether the Ninth Circuit's *Frye* Rule is considered a tool used in applying the standards of Article VII of the Federal Rules of Evidence or an independent judge-made rule.

During the debate over the proposed adoption of a federal evidence code, Judge Weinstein addressed the same federalism concerns raised by Petitioner. *See* J. Weinstein, *The Uniformity-Conformity Dilemma Facing Draftsmen of Federal Rules of Evidence*, 69 Colum. L. Rev. 353 (1969) (hereinafter "*Uniformity-Conformity*"). Judge Weinstein drew distinctions between rules that are associated with state substantive policies and purely procedural or "truth-determining" rules. Examples of rules that are associated with substantive rights are burdens of proof, presumptions, and evidentiary privileges. These rules are substantive under *Erie* principles because they are deliberately designed by the states to "affect substantive rights by favoring either plaintiffs or defendants." *Uniformity-Conformity*, 69 Colum. L. Rev. at 363. Burdens of proof and presumptions are designed to reach a preferred result that is consistent with an important state policy.

Likewise, privileges represent state policy decisions that exclusion of probative evidence is necessary to

promote relationships the state deems important.[2] *Id.* at 370. These rules raise federalism concerns because expressed substantive policies of the states favoring these relationships would be overridden if in such cases federal courts followed their own policies.

Rules concerning expert and opinion testimony are different. These rules do not promote relationships or favor one class of persons over another. They are designed to promote fairness and efficiency in the court's truth-finding function.[3] As such, they do not impair state substantive rights. If anything, the federal and the state policies are identical -- to find the truth.

Since there are no legitimate overriding state concerns, the federal courts should be allowed to apply the procedural rule they determine is best suited to the federal system of justice. *See* R. Degnan, *The Law of Federal Evidence Reform*, 87 Harv, L. Rev. 275, 298 (hereinafter, "*Evidence Reform*") ("Absent any applicable state policy, even occasional and unpredictable differences in outcome will not give offense to a state when the reason they occur is that superior fact finding machinery produced a closer approximation of truth than state processes were deemed capable of providing."); *cf. Haddigan v. Harkins*, 441 F.2d 844, 851-52 (3d Cir. 1970).

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[2] Such preferred relationships include husband-wife, attorney-client, and priest-penitent relationships. *See Uniformity-Conformity*, 69 Colum. L. Rev. at 370.

[3] As Judge Weinstein writes, rules controlling expert testimony are "clearly amenable to uniform treatment through federal rules of evidence. The hypothesis is that all of the rules are designed to achieve the same result, and divergence between state and federal practice is due only to some disagreement about which will achieve the better result in most cases." *Uniformity-Conformity*, 69 Colum. L. Rev. at 361. While some differences in outcome are inevitable, Judge Weinstein concludes that these must be ignored, "if the federal courts are to operate as an independent system with an integrity of its own." *Id.*

In *Byrd*, this Court acknowledged that uniformity of outcome is not the sole consideration under *Erie*. When "other considerations" such as the independence of the federal judiciary are present, this uniformity of outcome must give way. *Byrd*, 356 U.S. at 539. This is the case here.

II. THE *ERIE* DOCTRINE DOES NOT LIMIT CONGRESS'S POWER TO PROMULGATE PROCEDURE AND "TRUTH DETERMINING" RULES OF EVIDENCE THAT DO NOT IMPAIR SUBSTANTIVE STATE POLICIES

The federal courts may use the *Frye* Rule as a tool to apply the standards in Article VII of the Federal Rules of Evidence consistent with this Court's *Erie* jurisprudence.[4] Petitioners contend that Congress intended to exclude the *Frye* Rule from the Federal Rules of Evidence because Congress did not intend to infringe on substantive state rights and meant only to enact rules that did not tamper with state substantive policies. (Petitioners' Brief at 41-42.) This argument fails because the *Frye* Rule does not infringe upon substantive state policies.

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[4] There is substantial support for this position. *See United States v. Abel*, 469 U.S. 45, 51 (1984) (Court may look to pre-1975 decisions for guidance in interpreting Federal Rules of Evidence). The District Court used the principles of the *Frye* Rule in interpreting Fed. R. Evid. 703 and Fed. R. Evid. 403, finding that scientific evidence not "reasonably relied upon by experts in a particular field" should be excluded because evidence lacking this foundation would not be helpful and would confuse or mislead the jury. (Jt. App. at 229).

Other courts have followed this approach. *See, e.g., Richardson by Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 829 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989) (expert testimony based on theory not generally accepted lacked adequate foundation under Fed. R. Evid. 703); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 311-15 (5th Cir. 1987), *mod.*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990) (scientific speculation unconfirmed by epidemiological proof excluded under Fed. R. Evid. 703 and 402); *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190, 1194 (1st Cir. 1987) (inadequate foundation under Fed. R. Evid. 703).

A. Congress Did Not Consider Rules Governing the Admission of Expert Testimony To Be Substantive

Congress obviously did not believe that rules governing opinion testimony infringed on state substantive law. Expert testimony may be excluded under Article VII for a variety of reasons: if the opinion is not rationally based on the perception of a witness and is not helpful (Fed. R. Evid. 701); if the Court concludes the witness is unqualified (Fed. R. Evid. 702); if the Court determines the evidence will not assist the trier of fact to understand evidence or determine a fact in issue (Fed. R. Evid. 702); or, if there is no foundation for the opinion (Fed. R. Evid. 703). The Court also may exclude expert testimony if it determines it will not tend to make the existence of any fact of consequence to determination of the action more probable than not (Fed. R. Evid. 401). When Congress determined that the proposed evidentiary rules impinged upon State substantive policies, it rejected the proposed rules. Congress did so in three cases: Fed. R. Evid. 302 (presumptions), Fed. R. Evid. 501 (privilege) and Fed. R. Evid. 601 (competency of witnesses).[5]

Congress's acceptance of Article VII supports the conclusion that rules limiting expert testimony are not substantive *per se* in Congress's view. As Judge Weinstein points out, these truth-determining rules are procedural because they do not impair state substantive policies. *See Uniformity-Conformity*, 69 Colum. L. Rev. at 363.

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[5] In each instance, under diversity jurisdiction, the federal courts apply state law. In federal question cases, the courts are directed to apply general federal common law. *See* Fed. R. Evid. 501; *see also* C. Wright, *Law of Federal Courts* § 93, at 625-26 (1983).

B. The Federal Rules of Evidence May Override State Rules of Admissibility

Unlike other federal procedural rules, Congress adopted the Federal Rules of Evidence by statute. *See* Act of January 2, 1975, Pub. L. 93-595, 88 Stat. 1926 (1975). Accordingly, the Federal Rules of Evidence are not subject to the Rules of Decision Act, 28 U.S.C. § 1652, or the Rules Enabling Act, 28 U.S.C. § 2072. The Federal Rules of Evidence are judged under Article III of the Constitution and the Necessary and Proper Clause. As this Court stated in *Hanna v. Plumer*, 380 U.S. 460 (1965):

> The constitutional provision for a federal court system (augmented by the Necessary and Proper Clause) carries with it Congressional power to make rules governing the practices and pleading in those courts, which in turn includes a power to regulate matters which, though falling within the uncertain area between substance and procedure, are rationally capable of classification of either.

Hanna, 380 U.S. at 472. Since the Federal Rules of Evidence can be rationally viewed as rules of procedure, they are "unquestionably valid." O. Wellborn, III, *The Federal Rules of Evidence and the Application of State Law in the Federal Courts*, 55 Tex. L. Rev. 371, 398 (1977) (hereinafter, "*Federal Rules*").

Congress always has had the power to determine which evidence can be admitted in the federal courts. *See Tot v. United States*, 319 U.S. 463, 467 (1943). The Federal Rules of Evidence have been uniformly held to control in diversity cases. *See Forrestal v. Magendantz*, 848 F.2d 303, 305 (1st Cir. 1988) ("exclusion or admission of [expert] testimony is governed by the Federal Rules of Evidence in diversity cases"); *Salas by Salas v. Wang*, 846 F.2d 897 (3rd Cir. 1988); *Bushman v. Halm*, 798 F.2d 651, 660 n.6 (3rd Cir. 1986); ("it is axiomatic that admissibility of expert opinion is governed by the Federal Rules of Evidence"); *Garwood v. International*

Paper Co., 666 F.2d 217, 223 (5th Cir. 1982) (Federal Rules of Evidence govern admission or exclusion of expert testimony; reliance on state authority is misplaced).

Petitioners argue that the so-called "outcome-determinative" effect of the *Frye* Rule militates against interpreting the Federal Rules of Evidence as incorporating *Frye*. They rely on Professor Wellborn's argument that the Federal Rules of Evidence should be measured against the Rules Enabling Act requirement that procedural rules not abridge state-created rights. *See Federal Rules*, 55 Tex. L. Rev. at 400-01. Professor Wellborn's analysis of the relevancy rules, however, agrees with Judge Weinstein's conclusion that "truth-finding rules" do not have a substantive effect or infringe on state-created rights. He also concludes that such rules do not violate principles of federalism: "The purpose of the exclusion is to insure more accurate fact finding, not to promote some extrinsic social policy, and not to weight the scales in favor of one class of parties or another concerning any substantive right or duty intrinsically involved in the litigation." *Id.* at 395. *See Uniformity-Conformity*, 69 Colum. L. Rev. at 363.

Article VII applies across the board in all civil and criminal cases and favors neither plaintiffs nor defendants. No substantive rights are impaired by these rules, nor are conflicting state policies involved. The policy that the *Frye* Rule is intended to promote was explained by the Ninth Circuit:

> Expert opinion based on a scientific technique "is admissible if it is generally accepted as a reliable technique among the scientific community." . . . . We impose this requirement because such evidence "creates substantial danger of undue prejudice or of confusing the issues or of misleading the jury . . . because of its aura of special reliability and trustworthiness."

(Jt. App. at 238 (citations omitted)). *Frye*, therefore, is a truth-finding rule which does not abridge state-created rights and, thus, passes the Enabling Act test.

III. *FRYE* MAY BE SUSTAINED AS A JUDGE-MADE RULE INDEPENDENT OF THE FEDERAL RULES OF EVIDENCE UNDER *ERIE*

Petitioners alternately argue that the *Frye* Rule is a judge-made rule independent of the Federal Rules of Evidence which must fall under *Erie* because its application may lead to a different outcomes in certain cases. (Petitioners' Brief at 41.) The *Erie* doctrine is concerned only with substantive law: "Congress has no power to declare substantive rules of common law applicable in a State. . . . And no clause in the Constitution purports to confer such a power on the federal courts." *Erie*, 304 U.S. at 78.[6] This principle was reiterated by this Court in *Hanna*: "The broad command of *Erie* was therefore identical to that of the Enabling Act: federal courts are to apply state substantive law and federal procedural law." *Hanna*, 380 U.S. at 464.

The possibility that admission of evidence excluded by the *Frye* Rule could affect the outcome of a case does not render the Rule "outcome determinative" under *Erie*. In *Byrd*, this Court declined to require a federal court sitting in diversity to follow a state procedural rule mandating a bench trial where federal procedure required a jury trial. *Byrd*, 356 U.S. at 537. The Court recognized that application of federal procedure would affect the outcome:

> But there are affirmative countervailing considerations at work here. The Federal system is an independent system for administering justice to litigants who properly invoke its jurisdiction.

---

[6] The Court gave as examples "questions of purely commercial law . . . obligations under contracts . . . the liability for torts . . . . and the right to punitive damages." *Erie*, 304 U.S. at 75-76.

> An essential characteristic of that system is the manner in which, in civil common-law actions, it distributes trial functions between judge and jury and, under the influence -- if not the command -- of the Seventh Amendment, assigns the decision of disputed questions of fact to the jury. *Jacob v. City of New York*, 315 U.S. 752 [(1942)]. The policy of uniform enforcement of state created rights and obligations, *see, e.g., Guaranty Trust Co. of New York v. York*, [326 U.S. 99 (1945),] cannot in every case exact compliance with a state rule -- not bound up with rights and obligations -- which disrupts the federal system of allocating functions between judge and jury.

Id. at 537-538.

Under *Byrd*, therefore, federal courts are authorized to fashion "truth-finding" rules governing the admission and exclusion of evidence. Such rules apply across the board to all types of actions -- they are not "bound up with" rights and obligations created by the states. The *Frye* Rule is such a rule; it conflicts with no articulated substantive policy.

Any possible differences in outcome in particular cases arise from a variation of approach as to the best way to control the admission or exclusion of expert testimony. It is essential to the dignity and integrity of the federal courts (in the absence of direction from Congress) that they have the final say over the rules that govern the integrity of their proceedings. *See Monarch Ins. Co. v. Spach*, 281 F.2d 401, 407 (5th Cir. 1960). Professor Degnan has stated that, consistent with *Byrd*, exclusionary rules of evidence are part and parcel of those rules that distribute the trial functions between judge and jury:

> These rules govern distribution of "trial functions between judge and jury." Just as federal law determines the type of issues which must be submitted to a jury, so also should federal law

> decide what evidence a jury is entitled to hear and consider in resolving the issues submitted to it.

Evidence Reform, 87 Harv. L. Rev. at 294. He concludes:

> Exclusionary rules, which have little purpose other than affecting outcome (in the sense of ascertaining the fact picture), are not affected by *Erie*. . . . The *Byrd* case specifically holds that allocation of function between judge and jury is a federal question, and exclusionary rules are part of that allocation.

Id. at 301.

Finally, this Court also noted in *Byrd* that whether a judge or jury decides the issue does not determine the outcome of a case with certainty. The same is true with the application of the *Frye* Rule. While admission of evidence found incompetent or prejudicial under *Frye* would get a plaintiff to the jury, assuming the case is decided by a rational jury, the outcome would still be the same. Here, as in *Byrd*, an exclusionary rule should not be considered outcome-determinative for *Erie* purposes. *See Byrd*, 356 U.S. at 540.

CONCLUSION

The judgment of the United States Court of Appeals for the Ninth Circuit should be affirmed.

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Supreme Court of the United States
OCTOBER TERM, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE SUPPORTING RESPONDENT

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

No. 92-102

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,
Petitioners,
v.
MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE SUPPORTING RESPONDENT

INTEREST OF AMICUS CURIAE *

The Chamber of Commerce of the United States of America (the "Chamber"), a nonprofit corporation organized and existing under the laws of the District of Columbia, is the largest federation of business, trade, and professional organizations in the United States. It represents the interests of over 215,000 corporations, partnerships, and proprietorships, as well as state and local chambers of commerce and trade associations.

* Counsel for all parties have consented to the filing of this amicus brief. *Amicus* has filed those consents with the Clerk of this Court.

The problem of unreliable expert testimony presents grave concerns to the Chamber and its members. A tort system should be rationally designed to compensate injuries actually caused by tortious conduct; basing verdicts on unreliable expert testimony does not serve that goal. Lay juries often have a difficult time fully understanding or evaluating the nuances of competing scientific viewpoints, and are particularly unqualified to discard unreliable expert testimony which is admitted by the court. Because of this, a case which gets to a jury on the basis of unreliable expert testimony essentially gives that jury the option to follow its emotional impulse to "do justice" to the most sympathetic party. The Chamber believes that the result is a form of redistributive justice, largely divorced from the merits of the case. When the business community is taxed by verdicts in these otherwise-unsupportable cases, the effect is to deter the development and availability of goods and services that benefit the consumer.

The Chamber is filing this brief *amicus curiae* in support of respondent because it believes that the exclusion of unreliable scientific expert witness testimony from federal trials pursuant to the rule of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), is both important and required under the Federal Rules of Evidence. As we have noted, the exclusion of such unreliable testimony is important because its admission subverts the fairness of the trial process. The exclusion of such evidence is required because the *Frye* rule was the prevailing rule at the time the Federal Rules of Evidence were adopted, and there is no indication that the framers intended to abandon that rule. Even if adherence to *Frye* were not required, this Court should continue to follow the *Frye* rule as a matter of policy.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Chamber and Petitioners agree that unreliable expert testimony must be excluded (*see, e.g.*, Pet. Br. 38) and that the courts cannot adopt exclusionary rules that

are not sanctioned by the Federal Rules. So too, while a number of rules have been interpreted to require the exclusion of unreliable expert testimony, the Chamber agrees that Rule 403 of the Federal Rules of Evidence imposes limits on such testimony. *See* Pet. Br. 38-39.

Thus, the issue in this case is not whether there are any limits on the admissibility of expert testimony. The issue is what those limits are. In deciding what those limits are to be, the Court is presented with three options. One alternative is to retain the rule of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), which requires the exclusion of scientific evidence unless based on principles "generally accepted" by the scientific community. Another alternative is for the Court to craft a new test for district judges, much as the Third Circuit did in *United States v. Downing*, 753 F.2d 1224 (3d Cir. 1985). Or, the Court could embrace the position of Petitioners, and leave the admissibility of expert testimony to the *ad hoc* discretion of the district court under Rule 403.

This Court has made clear that statutes, including the Federal Rules of Evidence, are not to be construed to abrogate a common-law rule absent clear indications to the contrary. Since the rule of *Frye* was concededly the dominant rule at the time the Rules were adopted in 1975, *see* Pet. Br. 28, and there is no indication that Congress intended to alter that rule, the Rules should be construed to embody *Frye*. The history of the Federal Rules of Evidence supports the view that the framers intended the dominant *Frye* rule to continue.

In fact, one of the drafters' principal sources for drafting Rule 403 indicates that they understood *Frye* to be an application of that rule. The other two alternative approaches to unreliable expert testimony are simply inconsistent with the Rules. In any event, *Frye* reflects sound policy, and the other two approaches do not. *Frye* should not be changed except by amendment of the Federal Rules.

ARGUMENT

I. THE TEXT OF THE FEDERAL RULES OF EVIDENCE, THE RULES' HISTORY, AND THE UNIFORM ADHERENCE TO *FRYE* BEFORE THE PROMULGATION OF THE RULES ALL LEAD TO THE CONCLUSION THAT THE FEDERAL RULES INCORPORATED THE *FRYE* STANDARD.

A. The History Of Expert Testimony Shows That Its Reliability Has Always Been A Special Concern

In the early days of the common law in England, expert witnesses were unheard of; instead, where questions involving a special skill or technique were presented, the courts empaneled "special juries," which were made up of those familiar with the technical issues. For instance, where a tradesman was accused of improperly tanning hides, a special jury of tanners was empaneled.[1] "[T]he practice was well established in the fourteenth century of having the issue actually decided by people especially qualified." Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 Harv. L. Rev. 40, 42 (1901).

Thus, in cases involving a specialized discipline, there was no need to assure that the evidence was reliable before it went to the jury, because the jury itself was made up of a body of the people best suited to determine the reliability of the technical evidence. The present method, of using special witnesses to present their expertise to a lay jury, evolved from this practice, and had its earliest origins in the mid-fourteenth century. *Id.* However, the shift from expert juries to expert witnesses came at a price: No longer could the court ask the fact-finder to use its own expert knowledge to decide the case. Instead, the lay jury would have to rely on the expert

[1] Henry Thomas Riley, *Memorials of London and London Life in the 13th, 14th and 15th Centuries* 135, 420 (1868).

witness, but at the same time would lack the qualifications to determine the reliability of the expert.

As Judge Hand pointed out in 1901, "the expert is an anomaly," *id.* at 50, because he is simultaneously an authority in an area beyond the jury's comprehension, as well as a "witness" like any other.[2] With lay witnesses, a lay jury is expected to draw upon its collective knowledge "of the common affairs of life," *Sioux City & P. R.R. v. Stout*, 84 U.S. (17 Wall.) 657, 664 (1873), in order to determine credibility. But lay jurors cannot be expected to do the same when the credibility of an expert's opinion is at issue; there, "[t]he question should not turn simply on the external indicia of 'credibility'—as if some ordinary fact like the date of a telephone conversation were involved." *Julie Research Labs., Inc. v. Guildline Instruments, Inc.*, 501 F.2d 1131, 1133-34 (2d Cir. 1974).[3] The risks to litigants caused by unreliable expert testimony are serious. As Judge Weinstein has noted, experts can be found "to testify to the truth of almost any factual theory, no matter how frivolous, thus validating the case sufficiently to avoid summary judgment and force the matter to trial." Jack B. Weinstein, *Improving Expert Testimony*, 20 U. Rich. L. Rev. 473, 482 (1986). The cost of unreliable testimony is enormous: By forcing even the most tenuous cases to trial,

[2] A more recent commentator has also addressed the anomaly, noting that since "experts are called upon to draw inferences that are beyond the competence of ordinary people," lay juries cannot draw upon their traditional tools for making credibility determinations—because they are *lay* juries, they are by definition "incompetent to evaluate [the expert's] arguments." Samuel R. Gross, *Expert Evidence*, 1991 Wis. L. Rev. 1113, 1181.

[3] "Our reliance on lay juries to access the credibility of technical experts is not a problem, of course, if one is willing to assume that something magical happens in the jury room so that ordinary people can suddenly unravel complex technical and scientific issues that would baffle the rest of us." E. Donald Elliott, *Toward Incentive-Based Procedure: Three Approaches for Regulating Scientific Evidence*, 69 B.U. L. Rev. 487, 492 n.22 (1989).

the results are increased costs of litigation, enhanced risks of unjust results (which present virtually no ground for appeal), and an overburdened court system. Because of these concerns, it is universally accepted that the trial judge must impose some limits on the admissibility of expert testimony presented to a jury.

B. Rule 403 Of The Federal Rules Of Evidence Was Designed To Limit The Admissibility Of Unreliable Testimony, Including Expert Testimony.

This longstanding concern with the reliability of scientific expert testimony is reflected in the Federal Rules of Evidence. While there are several of the Federal Rules of Evidence that have been invoked to impose limitations on unreliable expert testimony,[4] this *amicus* agrees that the limitation is to be found in Rule 403 of the Federal Rules of Evidence, and that Rule 403 applies to the testimony of expert witnesses. Rule 403 provides:

> Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

Where Petitioners and the Chamber diverge is in the interpretation of Rule 403. The Chamber believes that Rule 403 incorporates the so-called *Frye* rule—the long-

[4] For instance, Rule 702 has been read to impose a limitation on the admissibility of expert testimony. That rule reads:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

This Rule should be read to impose the same limits on expert testimony as *Frye* and Rule 403. Under Rule 702, evidence which is not "generally accepted" by the relevant scientific community is simply not the "scientific knowledge" required by the Rule.

standing requirement that the principle "have gained general acceptance in the particular field . . . ." 293 F. at 1014. *Frye*'s theory is that if scientists would not rely upon the scientific "facts" being offered, there is no reason to allow lay jurors the chance to rely upon those so-called "facts."

The convergence between Rule 403 and *Frye* is obvious. The *Frye* rule proves to be nothing more than a recognition that "science" that is on the fringes, and has not been tested to the point of general acceptance across its disciplinary community, is always too potentially confusing, misleading, and prejudicial to be admitted, even if somewhat probative. Indeed, science that is on the fringes and thus unreliable satisfies *all* of the counterweights to probative value enumerated in Rule 403. Where the science is unreliable, there is a great possibility of *prejudice* to the opponent of that evidence, since the jury could possibly base its verdict on the unreliable evidence.[5] It would be *confusing* for the jury to hear the unreliable evidence, since scientific evidence is inherently complex, and the potential for confusion is increased exponentially when the jury has to assess whether the basic underlying principles are correct or incorrect. And, importantly, unreliable expert testimony would be potentially *misleading* for the jury, since science not "generally accepted" has an enhanced risk of being wrong.

As Professor Graham has noted, the *Frye* rule "merely states the conclusion derived from repeated application of Rule 403, that unless [the scientific technique has gained acceptance], its probative value simply cannot justify its potential for prejudice."[6] The Supreme Court of West

[5] *Accord* Fed. R. Evid. 403 Advisory Committee's Note (" 'Unfair prejudice' within its context means an undue tendency to suggest decision on an improper basis.").

[6] Michael H. Graham, *Handbook of Federal Evidence* § 703.2, at 656 (3d ed. 1991) (brackets in original; emphasis removed).

Virginia, interpreting Rules 403 and 702 of the Uniform Rules of Evidence, has similarly understood the relationship between the *Frye* rule and Rule 403 balancing:

> Certainly a test clothed with all the trappings of science, but which is not scientifically accepted, is more misleading or prejudicial than it is probative. Pseudo-science is more dangerous than no science at all. Therefore, at the end of the day we are all brought back essentially to the *Frye* rule with regard to tests that are not generally accepted . . . .

State v. Woodall, 385 S.E.2d 253, 259-60 (W. Va. 1989).[7]

While Rule 403 and *Frye* are similar in their goals, Rule 403, of course, does not explicitly adopt the *Frye* rule. However, "[b]ecause the Federal Rules of Evidence are a legislative enactment, we turn to the 'traditional tools of statutory construction,' . . . in order to construe their provisions." *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163 (1988) (quoting *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 (1987)). In cases where Congress is "working old ground" such as the common law, "the normal rule of statutory construction is that if Congress intends for legislation to change the interpretation of a judicially created concept, it makes that intent specific." *Midlantic Nat'l Bank v. New Jersey Dep't of Envtl. Protection*, 474 U.S. 494, 501 (1986). In other words, where a statute is enacted in the light of a common-law rule, that rule is deemed to survive absent clear evidence to the contrary.

This Court has twice specifically confirmed the same principle in the context of the Federal Rules of Evidence. In *Green v. Bock Laundry Machine Co.*, 490 U.S. 504,

[7] "Evidence that does not qualify under *Frye* must be excluded because, '[t]he prejudicial effect of an aura of scientific respectability outweigh[s] the slight probative value of the evidence.'" *United States v. Gillespie*, 852 F.2d 475, 480 (9th Cir. 1988) (quoting *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985)).

521-22 (1989), the Court read the Federal Rules to preserve the common-law right of all litigants to impeach witnesses by introducing evidence of a prior crime. Rule 609(a)(1), by its literal terms, allowed impeachment of testimony in civil cases only of "the defendant." The Court concluded that "[a] party contending that legislative action changed settled law has the burden of showing that the legislature intended such a change." *Id.* In *United States v. Abel*, 469 U.S. 45 (1984), a unanimous Court also held that impeachment of a witness for bias was permissible under the Federal Rules. As the Court noted, "the Rules do not by their terms deal with impeachment for 'bias,' although they do expressly treat impeachment by character evidence and conduct, Rule 608, by evidence of conviction of a crime, Rule 609, and by showing of religious beliefs or opinion, Rule 610." *Id.* at 49. However, the law before the Federal Rules of Evidence were promulgated unanimously allowed impeachment for bias. *Id.* at 50. Since there was a unanimity of common-law precedent, the Court found that even though the Rules were silent on the issue of impeachment for bias, it was "unlikely" that the drafters of the Federal Rules of Evidence "intended to scuttle entirely the evidentiary availability of cross-examination for bias." *Id.* The Court thus held that "it is permissible to impeach a witness by showing his bias under the Federal Rules of Evidence just as it was permissible to do so before their adoption." *Id.* at 51.

The principle to be derived from *Green* and *Abel* is that, where the Rules are silent on the retention of a common-law evidentiary rule, the common-law rule nonetheless can, and should, survive if it is consistent with the Rules. *Frye* plainly meets that standard.

C. At The Time That The Federal Rules Were Adopted In 1975, The Federal Courts Uniformly Adhered To The *Frye* Rule.

Petitioners agree that *Frye* was the dominant standard at the time the Federal Rules were adopted. Pet. Br. 38.[8] In *Frye v. United States*, 293 F. 1013, the trial court had refused to admit "lie detector" evidence which allegedly would have indicated defendant's innocence. The Court of Appeals agreed that such evidence had been properly excluded, because lie detector technology was too experimental and untested to risk submitting to a jury:

> Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.

Id. at 1014. The court thus recognized that "the best test of truth is the power of the thought to get itself accepted" in the marketplace of ideas, *i.e.*, the scientific community.[9]

Four years after *Frye* was decided, Professor McCormick called it "the only decision on the point that has come to my attention." Charles T. McCormick, *Deception-Tests and the Law of Evidence*, 15 Cal. L. Rev. 484, 499 (1927). Thereafter, every circuit to face the issue of the admissibility of scientific expert testimony before the passage of the Federal Rules of Evidence followed the *Frye* rule. By July 1, 1975, when the Federal

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[8] *See also* Br. *Amicus Curiae* of A Group of American Law Professors 6.

[9] *Abrams v. United States*, 250 U.S. 616, 630 (1919) (Holmes, J., dissenting).

Rules of Evidence became law, *Frye* had been embraced by six of the then eleven judicial circuits: the D.C.,[10] Fifth, [11] Sixth,[12] Eighth,[13] Ninth,[14] and Tenth [15] Circuits. *Frye* also had never been rejected by any federal circuit when the Federal Rules of Evidence were adopted. Indeed, when the Federal Rules were adopted, there was no competing rule in the federal courts for the admission or exclusion of scientific evidence.

The *Frye* rule was also overwhelmingly followed by the states before the Federal or Uniform Rules of Evidence were promulgated. In *Reed v. State*, 391 A.2d 364, 368 (Md. 1978), the Court of Appeals of Maryland surveyed the states that had "considered the question of the admissibility of scientific evidence," and concluded that the *Frye* rule "has come to be the standard in almost all of the courts in the country" to have considered the question. *Id.* (citing cases). Even Petitioners and one *amicus curiae* recognize that the *Frye* test was "notorious," Pet. Br. 28, and "dominant," [16] in 1975.

D. The Framers Of The Federal Rules Of Evidence Did Not Reject The *Frye* Rule.

The language and history of the Federal Rules do not evidence any rejection of the then-unanimous view that the rule of *Frye* was the appropriate rule for dealing with the admissibility of expert scientific evidence.

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[10] *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).

[11] *United States v. Frogge*, 476 F.2d 969, 970 (5th Cir.), *cert. denied*, 414 U.S. 849 (1973).

[12] *United States v. McDevitt*, 328 F.2d 282, 284 (6th Cir. 1964).

[13] *McCroskey v. United States*, 339 F.2d 895, 897 (8th Cir. 1965).

[14] *Lindsey v. United States*, 237 F.2d 893, 896 (9th Cir. 1956).

[15] *Marks v. United States*, 260 F.2d 377, 382 (10th Cir. 1958), *cert. denied*, 358 U.S. 929 (1959).

[16] Br. *Amicus Curiae* of A Group of American Law Professors 6.

The Federal Rules of Evidence were the product of a debate between two views of how properly to codify the law of evidence. One school, the one most nearly followed by the Federal Rules of Evidence, took the position that a codification of evidence law should serve to compile and condense the existing rules. 21 Charles Alan Wright & Kenneth W. Graham, Jr., *Federal Practice and Procedure* § 5005, at 63 (1977). The other, more "radical" view was that codification should completely reshape the law. The latter, of course, required a much more comprehensive effort.

The first major effort to draft a code of evidence in this century was the American Law Institute's (ALI) Model Code of Evidence, and there, "[t]he issue which first divided the Reporter and the Chief Consultant concerned the form of the Code. One possibility was a very condensed set of rules like the Federal Rules of Civil Procedure, a format [urged] by Judge Charles E. Clark, the draftsman of the Federal Rules [of Civil Procedure]." *Id.* at 85. The other option was the one advocated by Dean Wigmore, who "wanted to follow the example of his own Code of Evidence, a set of finely detailed rules that ran to over five hundred pages." *Id.* at 86 (footnotes omitted). A middle ground between the two extremes was embraced by the finished ALI Model Code. *Id.*; *see generally* ALI, *Model Code of Evidence* (1942).

The ALI Model Code "did not catch on as a vehicle for reform. Although it was cited in a few appellate opinions, it was never seriously considered for adoption by any state except Nebraska," 21 Wright & Graham, *supra*, § 5005, at 88-89, perhaps because of the unsatisfactory nature of the compromise it sought to make. As a result, "the baton of reform" was passed to the National Conference of Commissioners on Uniform State Laws (NCCUSL). *Id.* at 89. The NCCUSL took as its outline the ALI Model Code, but followed a much less radical course: "The only sort of reform that was found

compatible with the goal of acceptability was the elimination of 'obsolete and unsound relics' of the past." *Id.* at 90 (quoting Spencer Gard, *The New Uniform Rules of Evidence*, 2 Kan. L. Rev. 333, 341 (1954)). The result was a set of rules, issued in 1953, which were much "closer to the brevity and simplicity that Judge Charles Clark had advocated for the Model Code" than to the comprehensiveness advocated by Wigmore. 21 Wright & Graham, *supra*, § 5005, at 90-91.[17]

On March 13-14, 1961, Chief Justice Warren appointed a "Special Committee on Evidence" to consider whether or not uniform federal rules of evidence were feasible. The Special Committee, nine months later, concluded that uniform rules were both desirable and feasible, and should be undertaken through the rulemaking process, because a "comprehensive, thorough and consistent revision cannot be obtained through scattered decisions." [18] In support of this observation, the Special Committee cited *Michelson v. United States*, 335 U.S. 469, 486 (1948), where the Court said that, since it could "make only infrequent sallies into the field" of evidence, it would not adopt a new rule of evidence which was largely rejected at common law.[19] The Special Committee also concluded that the Uniform Rules of Evidence should be adapted to create the new Federal Rules of Evidence.[20]

The drafters and framers of the Federal Rules of Evidence did just that, opting for a "handy pamphlet"

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[17] The goal of the Uniform Rules "was 'to express the rules in simple language and in convenient usable form,' a goal easier to reach when one is simply stating a system everyone knows than when one is striving to set forth a new set of rules." 21 Charles A. Wright & Kenneth W. Graham, Jr., *Federal Practice and Procedure* § 5005, at 90-91 (1977) (quoting Spencer Gard, *The New Uniform Rules of Evidence*, 2 Kan. L. Rev. 333, 338 (1954)).

[18] *A Preliminary Report on the Advisability and Feasibility of Developing Uniform Rules of Evidence for the United States District Courts*, 30 F.R.D. 73, 115 (1962) ("*Advisability and Feasibility*").

[19] *See id.* at 116.

[20] *Id.* at 110-13.

form modeled on the Uniform Rules.[21] The Rules were meant to be complete, but not comprehensive in the style of Wigmore. When the Advisory Committee first set to its task, it decided to "strike a middle course between vague generalities and constricting particularity."[22] A Preliminary Draft of the Federal Rules of Evidence was published and circulated for public comment in March 1969. Numerous changes were suggested by the bench and bar, leading to a "Revised Draft," which, after further changes, was approved by the Judicial Conference, promulgated by the Court and sent to Congress pursuant to the Rules Enabling Act.[23]

But these Rules were held up by Congress, which was principally concerned with the privilege rules in Article V.[24] As a result, the Federal Rules of Evidence were ultimately not promulgated through the rulemaking processes, as were the Federal Rules of Civil and Criminal Procedure, but as a traditional bill. The result was the Federal Rules of Evidence, which have governed evidence in federal trials since July 1, 1975, and which exist today in virtually the same form, with the exception of a few technical changes made since 1975.

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[21] *See Proposed Rules of Evidence: Hearings Before the Subcomm. on Reform of Federal Criminal Laws of the House Comm. on the Judiciary*, 93d Cong., 1st Sess. 34 (1973) (testimony of Albert Jenner, Jr., Chairman of the Advisory Committee) (*"Hearings Before the Subcomm. on Reform of Federal Criminal Laws"*).

[22] *Id.* at 91 (testimony of Professor Edward W. Cleary, Reporter to the Advisory Committee).

[23] 21 Wright & Graham, *supra* n.17, § 5006, at 100, 101.

[24] The result was that the proposed rules on privilege gave way to the Congressionally-drafted Fed. R. Evid. 501, which now states that privilege "shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience." In cases where state law supplies the rule of decision, privilege "shall be determined in accordance with State law."

There is no indication that either the Advisory Committee or Congress intended to scrap the "notorious" and "dominant" *Frye* rule. The Advisory Committee's Notes,[25] the legislative history,[26] as well as the minutes of the meetings held by the Advisory Committee on Evidence[27] are devoid of any suggestion that *Frye* was being repealed.

Numerous commentators have understood this silence as retaining the *Frye* rule under the Federal Rules of Evidence. Professors Saltzburg and Martin have concluded that "it was highly unlikely the Advisory Committee and the Congress intended to overrule the vast majority of cases excluding such evidence as lie detectors without explicitly stating so." 2 Steven A. Saltzburg & Michael M. Martin, *Federal Rules of Evidence Manual* 15 (5th ed. 1990). *See also* 1 David Louisell & Christopher Mueller, *Federal Evidence* § 105, at 818 (1977); Michael H. Graham, *supra*, § 703.2, at 655.[28] Even the leading case purporting to depart from the *Frye* standard,

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[25] *See Rules of Evidence for United States Magistrates: Amendments*, 56 F.R.D. 183 (1973); *Revised Draft of Proposed Rules of Evidence for the United States Courts and Magistrates*, 51 F.R.D. 315 (1971) (earlier draft); *Preliminary Draft of Proposed Rules of Evidence for the United States District Courts and Magistrates*, 46 F.R.D. 161 (1969).

[26] *See* H.R. Conf. Rep. No. 1597, 93d Cong., 2d Sess. (1974), *reprinted in* [1974] U.S.C.C.A.N. 7098; H.R. Rep. No. 650, 93d Cong., 1st Sess. (1973), *reprinted in* [1974] U.S.C.C.A.N. 7075; S. Rep. No. 1277, 93d Cong., 2d Sess., *reprinted in* [1974] U.S.C.C.A.N. 7051; *Rules of Evidence: Hearings on H.R. 5463 Before the Senate Comm. on the Judiciary*, 93d Cong., 2d Sess. (1974); *Hearings Before the Subcomm. on Reform of Federal Criminal Laws.*

[27] *See, e.g., Minutes of Meeting—Advisory Committee on Evidence* 30-39 (Feb. 3-5, 1966).

[28] Judge Weinstein and Professor Berger appear to draw the opposite conclusion, but do so in equivocal language: the "silence of [Rule 702] and its drafters *may arguably be regarded as tantamount to* an abandonment of the general acceptance standard." 3 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Evidence* ¶ 702[03], at 702-36 (1992) (emphasis added).

United States v. Downing, 753 F.2d 1224, 1235 (3d Cir. 1985), agreed that the Federal Rules of Evidence did not repudiate *Frye*.[29]

The absence of any suggestion that *Frye* should be abolished is, under this Court's decisions, more than sufficient to preserve *Frye*. But there is more. First, the drafters of the Federal Rules of Evidence specifically confirmed that they were not seeking to entirely rewrite the law of evidence.[30] As the Reporter of the Advisory Committee wrote, "The legal background against which the Rules were drafted and enacted was a vast collection of common law precedents. . . . Thus the Rules were working old ground, and ground that was near and dear to much of the profession."[31] As this Court noted in *Abel*, it was clear that the framers intended that "the body of common law knowledge continue to exist [as] a source of guidance in the exercise of delegated powers." *United States v. Abel*, 469 U.S. at 51-52 (quoting Edward W. Cleary, *Preliminary Notes on Reading the Rules of Evidence*, 57 Neb. L. Rev. 908, 915 (1978)) (internal quotations omitted).

Second, in the few instances where the drafters departed from a traditional common-law rule, they made

[29] The McCormick treatise also argues against retention of the *Frye* rule, but does so based on "policy" concerns, not the text of the Federal Rules. *See* 1 *McCormick on Evidence* § 203, at 874 (4th ed. 1992).

[30] *See Advisability and Feasibility*, 30 F.R.D. at 110.

[31] Edward W. Cleary, *Preliminary Notes on Reading the Rules of Evidence*, 57 Neb. L. Rev. 908, 909 (1978). *See also* 10 James William Moore & Helen I. Bendix, *Moore's Federal Practice* § 1, at 5 (2d ed. 1988) ("The Federal Rules of Evidence are rooted in the past. . . . There is nothing revolutionary about them."). The Chairman of the Advisory Committee, Albert E. Jenner, Jr., expressed similar views in hearings before the House of Representatives, stating that the Committee was not "inclined to give the family jewels away or tip or rock the laws of evidence." 21 Wright & Graham, *supra* n.17, § 5006, at 99.

their intent clear. For instance, Fed. R. Evid. 607 allows the credibility of a witness to be attacked by any party, a departure from common law. The first sentence of the Advisory Committee's Note reads: "The traditional rule against impeaching one's own witness is abandoned as based on false premises." Similar language appears where other common-law rules were discarded.[32] There is no similar language discarding, or even relaxing, the *Frye* rule.

Third, the drafters of the Federal Rules specifically contemplated that the principles of Rule 403 would be embodied in specific rules. Rule 403 is described by the Advisory Committee's Note as "designed as a guide for the handling of situations for which no specific rules have been formulated," noting that the "rules which follow in this Article are concrete applications evolved for particular situations." In other words, Rule 403 articulates a general principle that may be embodied in a specific rule, such as *Frye*.

Finally, the Advisory Committee's Note to Rule 403 suggests that the drafters were aware of *Frye*, and believed it to be relevant to Rule 403. In framing Rule 403, the drafters relied on Professor Herman L. Traut-

[32] *See also* Fed. R. Evid. 613(a) Advisory Committee's Note ("The rule abolishes this useless impediment"); Fed. R. Evid. 613(b) Advisory Committee's Note (requirement that an impeaching statement be shown to the witness before it can be proved by extrinsic evidence "is preserved but with some modifications"); Fed. R. Evid. 704 Advisory Committee's Note ("the so-called 'ultimate issue' rule is specifically abolished by the instant rule"); Fed. R. Evid. 705 Advisory Committee's Note (eliminating requirement of preliminary disclosure of facts and data underlying expert opinion); Fed. R. Evid. 804(b)(3) Advisory Committee's Note ("The exception discards the common law limitation and expands to the full logical limit"); Fed. R. Evid. 804(b)(4) Advisory Committee's Note ("The general common law requirement that a declaration in this area must have been made *ante litem motam* has been dropped"); Fed. R. Evid. 1001 Advisory Committee's Note (relaxing the "best evidence rule").

man's seminal article, *Logical or Legal Relevancy—A Conflict in Theory*, 5 Vand. L. Rev. 385 (1952). Professor Trautman's article addresses the "Conflict in Theory" between "logical relevancy," which is the tendency of Fact A to prove the existence of Fact B, *id.* at 385, and "legal relevancy," which allows the exclusion of otherwise logically-relevant evidence based on "considerations of policy." *Id.* at 395-96. The Federal Rules of Evidence retain this distinction in Rule 401, the "logical relevancy" rule, and Rule 403, the "legal relevancy" rule.

Importantly, Professor Trautman's article includes an extended discussion of the *Frye* rule. *Id.* at 395-96 & n.37. He saw *Frye* as a product of a "legal relevancy" inquiry, which would now take place under Rule 403. Indeed, he conceded that lie detector tests (the issue in *Frye*) would be logically relevant, but that "considerations of policy (perhaps a judicial fear of undue prejudice in the minds of the jury resulting from a lack of proper administrative standards for controlling the competency of the operator, the type of machine used and the circumstances under which it is used)" provided a "rational basis" for exclusion. *Id.* at 396. Thus, Professor Trautman's article is the only available evidence that the framers considered the *Frye* rule, and it clearly indicates that they thought *Frye* to be an appropriate product of a Rule 403 inquiry.

The design and history of the Federal Rules thus plainly support the preservation of *Frye*.[33] They are also directly inconsistent with Petitioners' view that Rule 403 authorizes only *ad hoc* balancing. Indeed, as Petitioners have themselves advocated, "one of Congress's most funda-

[33] Any suggestion that the framers of the Rules believed it was impracticable to ascertain the relevant scientific community and its views is contradicted by Rule 703, which allows an expert to base his opinion upon facts or data "reasonably relied upon by experts *in the particular field* in forming opinions or inferences upon the subject," even though the facts or data are not admissible in evidence. (emphasis added).

mental policy choices in enacting the Federal Rules of Evidence [was] its desire to bring *uniformity* to federal evidence law." Pet. Cert. 16 (emphasis in original). Applying *ad hoc* balancing to scientific expert testimony would create even more disparity than the current circuit conflict over *Frye*: Instead of varying among the circuits, the admissibility of scientific expert testimony could vary on a district judge-by-district judge basis or even a case-by-case basis.

E. The Mechanism For Changing An Established Rule Of Evidence Is The Rulemaking Process.

The other alternative approach to unreliable expert testimony—the drafting of a new Rule in the adjudicatory context—is also inconsistent with the design of the Federal Rules. If the *Frye* rule is to be changed, it should be changed through either the legislative or the rulemaking processes, not through adjudication. When the Federal Rules were adopted in 1975 this legislative approach was seen as far preferable to judicial rulemaking.[34] The very premise of the Federal Rules was that revision in the laws of evidence "cannot be obtained through scattered decisions." [35]

There is little question that a mechanism is available to make changes in the Federal Rules of Evidence through the Rules Enabling Act. Indeed, the Standing Committee within the last year has considered changes in the Rules concerning the admissibility of expert testimony. The Advisory Committee on Civil Rules approved, with one member dissenting, a "controversial" amendment to Rule 702 that was "intended to limit the use, but increase the utility and reliability, of party-initiated opinion tes-

[34] *See, e.g., Advisability and Feasibility*, 30 F.R.D. at 100-05.

[35] *Id.* at 115. "Improvements in evidence law ha[ve] to come through codification. . . ." Thomas M. Mengler, *The Theory of Discretion in the Federal Rules of Evidence*, 74 Iowa L. Rev. 413, 429 (1989).

timony bearing on scientific and technical issues." [36] As proposed, Rule 702 would have required that the testimony be "reasonably reliable" and "substantially assist" the trier of fact.[37] However, the Standing Committee on Rules of Practice and Procedure, the last step before transmission to the Judicial Conference of the United States, demurred. Instead, the Standing Committee "[e]ndorsed a request to the Chief Justice that he reactivate an Advisory Committee on the Federal Rules of Evidence" and "appoint a reporter to serve the reactivated Evidence Rules Committee." [38] The Chief Justice has done so, and Judge Ralph K. Winter of the Second Circuit has been appointed chairman. With the revitalization of an evidence committee, it is to be expected that a more active dialogue among bench, bar, and academia concerning the Rules will take place. Changes in the Rules of Evidence should originate with that committee and be enacted through the rulemaking process rather than adopted in the context of adjudication.

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[36] Committee on Rules of Practice and Procedure of the Judicial Conference of the United States, *Preliminary Draft of Proposed Amendments to the Federal Rules of Civil Procedure and the Federal Rules of Evidence*, Committee Notes (1991). *See also* Letter from Hon. Sam C. Pointer, Chairman, Advisory Committee on Civil Rules to Hon. Robert E. Keeton, Chairman, Standing Committee on Rules of Practice and Procedure, Attachment B, at 14 (May 1, 1992).

[37] While the Proposed Advisory Committee's Note to Proposed Rule 702 correctly stated that "the admissibility of such evidence is, and remains, subject to the general principles of 403," it curiously went on to assert that the Proposed Rule "does not mandate a return to the strictures of *Frye v. United States*." There is no support provided for the apparent assumption that *Frye* has been eliminated, and the Committee Notes to an unenacted Rule are entitled to no deference. *Cf. Puerto Rico Dep't of Consumer Affairs v. Isla Petroleum Corp.*, 485 U.S. 495, 501 (1988).

[38] Judicial Conference of the United States, *Preliminary Report, Judicial Conference Actions* at 8 (Sept. 22, 1992).

II. EVEN IF THE *FRYE* RULE WERE NOT REQUIRED BY THE FEDERAL RULES, IT SHOULD BE FOLLOWED BY THIS COURT BECAUSE IT IS THE BEST AVAILABLE ALTERNATIVE FOR EXCLUDING UNRELIABLE EXPERT TESTIMONY.

Even if the *Frye* rule were not compelled by the Federal Rules of Evidence, it should be followed by this Court. Of the three options available to this Court—the *Frye* rule, a new test, or *ad hoc* balancing—*Frye* is by far the preferable alternative. It is the standard most familiar to judges and litigants, and it provides the most appropriate standard for the balancing required by Rule 403.

A. The *Frye* Rule.

As Professor Cleary has aptly noted, "Evidence, more than any other field of law, calls for making decisions on the run." [39] As the long-standing rule for the admissibility of scientific expert testimony, the federal courts are intimately familiar with the *Frye* rule, and they have repeatedly utilized its "general acceptance" standard to exclude unreliable scientific testimony. But there is far more to recommend the *Frye* rule than the federal courts' longstanding familiarity. The *Frye* rule has the advantage of making it unnecessary for the courts themselves to determine whether particular scientific expert testimony is reliable or unreliable, a task that judges are often ill-equipped to undertake in this age of increasing scientific complexity. Rather, the *Frye* rule focuses the attention of the courts where it belongs—on the question of general acceptance in the scientific community.[40]

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[39] *Hearings Before the Subcomm. on Reform of Federal Criminal Laws* at 547 (testimony of Professor Edward W. Cleary, Reporter to the Advisory Committee).

[40] Moreover, the *Frye* rule, by requiring a "general acceptance" in the relevant scientific community, assures that there will be an adequate pool of rebuttal experts for the opposing party to draw

The *Frye* rule also ensures consistency in the law of evidence. Instead of creating a situation in which each judge in each case will make an *ad hoc* determination of admissibility, it ensures consistency. For instance, if the Ninth Circuit had concluded in one case that the opinion of an "accidentologist," based on the statements of bystanders, was unreliable proof of the point of impact in a suit arising out of an automobile collision,[41] the next district court asked to admit the testimony of an "accidentologist" would be required to exclude it.

Finally, the *Frye* rule is flexible and allows for change as the state of scientific knowledge changes. A ruling in one case that certain scientific evidence is inadmissible does not foreclose the possibility that the evidence could be admitted in a future case. Perhaps the best illustration of *Frye*'s contribution to the "growth and development of the law of evidence," Fed. R. Evid. 102, is seen by comparing *Frye* with *United States v. Piccinonna*, 885 F.2d 1529 (11th Cir. 1989) (en banc). In *Frye*, the District of Columbia Circuit concluded that lie detectors had not gained sufficient general acceptance in scientific arenas to assure the court of their reliability. In *Piccinonna*, however, the Eleventh Circuit revisited the question of admissibility "[i]n the wake of new empirical evidence and scholarly opinion which have undercut many of the traditional arguments against admission of polygraph evidence," *id.* at 1533, and concluded that polygraph evidence could be admitted at trial.[42]

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upon. *See, e.g., United States v. Addison*, 498 F.2d 741, 744 (D.C. Cir. 1974).

[41] The example is taken from Fed. R. Evid. 703 Advisory Committee's Note.

[42] Some have criticized the *Frye* rule as being an unduly "conservative" standard for evaluating science, a position which is embraced by various *amici*. For instance, *amici* Physicians, Scientists, and Historians of Science champion the "eccentrics" of science, such as Galileo, whose testimony would (presumably) have been excluded in his day because he challenged the "geocentric

The virtues of *Frye* have manifested themselves in the federal courts' virtually unflagging adherence to *Frye*, even after the passage of the Federal Rules of Evidence. Since the passage of the Federal Rules, even more circuits have embraced the *Frye* rule. The District of Columbia Circuit has continued to follow *Frye*.[43] The First Circuit has joined the ranks of the followers of *Frye*, relying upon it to exclude polygraph evidence in a civil case.[44] The Fourth Circuit, which Petitioners claim to have rejected *Frye*, *see* Pet. Br. 17 n.44, has nonetheless indicated that the admissibility of expert testimony is "dependent upon some degree of proven acceptance within the appropriate discipline."[45] The Fifth[46] and Sixth[47] Circuits still follow *Frye*. The Seventh Circuit, which prior to 1975 had not addressed the issue, has adopted *Frye* into its case law.[48] The Eighth Circuit recently said that it viewed Fed. R. Evid. 702 and *Frye* "as

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orthodoxy promoted by the Aristotelian scientists who dominated the academies and universities." Br. *Amici Curiae* of Physicians, Scientists, and Historians of Science 14-15. Admittedly, there is a cost in excluding expert testimony on the fringes, for time may ultimately prove it to be reliable. But, as the D.C. Circuit said in *United States v. Addison*, 498 F.2d at 743, "This is not to say . . . that the *Frye* standard exacts an unwarranted cost."

[43] *United States v. Shorter*, 809 F.2d 54, 59-61 (D.C. Cir.), *cert. denied*, 484 U.S. 817 (1987) ("*Frye* is still the law in this Circuit").

[44] *de Vries v. St. Paul Fire & Marine Ins. Co.*, 716 F.2d 939, 945 (1st Cir. 1983).

[45] *United States v. Gould*, 741 F.2d 45, 49 n.2 (4th Cir. 1984).

[46] *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1110 (5th Cir. 1991) (per curiam) (en banc), *cert. denied*, 112 S. Ct. 1280 (1992).

[47] *United States v. Metzger*, 778 F.2d 1195, 1203 (6th Cir. 1985), *cert. denied*, 477 U.S. 906 (1986); *see also Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188, 1208 (6th Cir. 1988).

[48] *United States v. Smith*, 869 F.2d 348, 350-54 (7th Cir. 1989).

generally compatible and not as mutually exclusive." [49] The Ninth Circuit still continues to embrace *Frye*,[50] as does the Tenth Circuit,[51] and the *en banc* Eleventh Circuit relied on *Frye* in concluding that lie detectors had gained sufficient acceptance to be admissible in the district court's discretion.[52]

Most of the states which have adopted the Uniform Rules of Evidence also recognize the virtues of *Frye*. In fifteen of the states where the Uniform Rules of Evidence have been adopted, *Frye* still is the standard for the admissibility of expert scientific testimony.[53]

B. The Alternative "Tests".

A second option for this Court is to craft its own test for the exclusion of unreliable expert testimony, based on a variety of judicially-created "tests," as well as a number of alternatives proposed by commentators. However, it can quickly be seen that the available options have none of the virtues of the *Frye* test. They are not familiar to the vast majority of district judges. And they are much too complex for any district judge to utilize "on the run."

The difficulty with these tests is readily apparent. For example, in *United States v. Downing*, the Third Circuit divined a creative, "flexible" test for the admis-

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[49] *United States v. Two Bulls*, 918 F.2d 56, 60 n.7 (8th Cir. 1990), *appeal dismissed*, 925 F.2d 1127 (8th Cir. 1991).

[50] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128, 1129-30 (9th Cir. 1991), *cert. granted*, 113 S. Ct. 320 (1992); J.A. 238 (same).

[51] *United States v. Smith*, 776 F.2d 892, 898 (10th Cir. 1985).

[52] *United States v. Piccinonna*, 885 F.2d 1529, 1531-32 (11th Cir. 1989) (en banc).

[53] The states where the Uniform Rules of Evidence govern and *Frye* is still followed are listed, along with representative cases, in an Appendix to this Brief.

sibility of novel scientific evidence. In order for the district courts of the Third Circuit to determine whether scientific evidence is "reliable," and thus admissible the courts must follow the factors announced in this test:

> (1) Explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community.
>
> (2) The "novelty" of the new technique; that is, "its relationship to more established modes of scientific analysis."
>
> (3) The existence of a specialized literature dealing with the technique.
>
> (4) The qualifications and professional stature of expert witnesses, and the non-judicial uses to which the scientific technique is put.
>
> (5) The frequency with which a technique leads to erroneous results.
>
> (6) The district court may take judicial notice of expert testimony that has been offered in earlier cases to support or dispute the merits of a particular scientific procedure.
>
> (7) "Undoubtedly, other factors could be added to the list."

753 F.2d at 1238-39. The district court on remand in *Downing* was forced to write a comprehensive opinion addressing the *Downing* factors in order to conform to the Third Circuit's mandate. *See United States v. Downing*, 609 F. Supp. 784 (E.D. Pa. 1985), *aff'd mem.*, 780 F.2d 1017 (3d Cir. 1985).[54] In addition to its cumber-

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[54] Similarly, in *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990), the Third Circuit reversed and remanded the district court's grant of summary judgment for defendants, on the ground that the record did not support the exclusion of the plaintiffs' expert's testimony under the *Downing* test. On remand,

some nature, the *Downing* test is one which is not familiar to most district judges; indeed, it probably would never become familiar due not only to its prolixity, but also to its open-endedness. As "other factors" continue to be added to the list, the test will constantly change.

The test proposed by *amicus* The Carnegie Commission on Science, Technology and Government is no less cumbersome and complex, and threatens, like *Downing*, to turn courtrooms into research laboratories. The Carnegie Commission suggests that a three-pronged inquiry be adopted, involving (1) the testability of the "claim being put forth" by the expert, (2) whether the claim has been empirically tested, and (3) whether the testing has "been carried out according to a scientific methodology." Br. *Amicus Curiae* of the Carnegie Commission on Science, Technology and Government 11. Prong one would require courts to "identify the line of demarcation between science and non-science," a line which the Carnegie Commission concedes "Courts have rarely sought" to do. *Id.* at 12. Prongs two and three would require courts to inquire into the scientific testing of the expert's hypothesis, an inquiry that would require courts to venture into the laboratory to determine "whether appropriate testing occurred," *id.* at 17, as well as what constitutes "appropriate testing."

Some state courts and some commentators have also attempted to propose alternative tests. The results have been as complex as *Downing*, and in some instances even more so. Oregon, for example, has a seven-factor reliability "filtration" test, which was set out in *State v. Brown*, 687 P.2d 751, 759 (Or. 1984) (en banc). The Oregon test includes such factors as (1) the technique's

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the district court "conducted a hearing held on five separate days, followed by extensive post-hearing submissions of the parties, in order to determine whether Dr. Done's testimony is admissible under the criteria set forth in *United States v. Downing*." *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 791 F. Supp. 1042, 1044 (D. N.J. 1992).

general acceptance, (2) the expert's qualifications and stature, (3) the use which has been made of the technique, (4) the potential rate of error, (5) the existence of specialized literature, (6) the novelty of the invention, and (7) the extent to which the technique relies on the subjective interpretation of the expert.

Another typical alternative to the *Frye* rule was suggested in a law review article. There, the commentator proposed an even more elaborate, *eleven*-factor analysis to guide trial judges in the admissibility of scientific evidence. Under this test, factors to be taken into account "include" (1) the potential error rate of the technique, (2) the existence and maintenance of standards governing its use, (3) the presence of safeguards in the characteristics of the technique, (4) analogies to other scientific techniques whose results are admissible, (5) the extent to which the technique has been accepted by scientists in the field involved, (6) the nature and breadth of the inference adduced, (7) the clarity and simplicity with which the technique can be described and its results explained, (8) the extent to which the basic data are verifiable by the court and jury, (9) the availability of other experts to test and evaluate the technique, (10) the probative significance of the evidence in the circumstances of the case, and (11) the care with which the technique was employed in the case. Mark McCormick, *Scientific Evidence: Defining a New Approach to Admissibility*, 67 Iowa L. Rev. 879, 911-12 (1982).

The available alternatives to the *Frye* rule are cumbersome, open-ended, multi-factor tests which are, to put it charitably, almost impossible to apply. Plainly, then, the adoption of a new substantive rule in place of *Frye* is wholly unsatisfactory.

C. "Ad Hoc, Case-Specific Balancing".

The last alternative to *Frye* is the one advocated by the Petitioners—"[*A*]*d hoc*, case-specific balancing." *See*,

e.g., Pet. Br. 38. Petitioners' solution to the problem of unreliable expert testimony is to leave such rulings to the largely unbridled discretion of the district court. Taken to its logical extension, Petitioners' position is that appellate cases decided under the Federal Rules of Evidence have no precedential value, because the district court writes on a clean slate every time it makes an evidentiary ruling. This approach is as wrong as it is unusual. Appellate courts routinely announce factors necessary to a trial court's exercise of discretion, and these factors necessarily cabin that discretion in future cases.[55]

Vesting *ad hoc*, unprincipled discretion in the decisionmaker does not lead to the "fairness" envisioned by Rule 102; on the contrary, it is the most likely course to injustice. Kenneth Davis, *Discretionary Justice: A Preliminary Inquiry* v (1971). The source of this unfairness is readily apparent. The litigants would have no meaningful recourse to higher authority. In an era of litigation explosion, a single product or a single event may generate multiple lawsuits in widely scattered geographic areas, and often the same scientific expert testimony is offered in many of these lawsuits, as has been the case with Bendectin. Under Petitioners' proposal, different federal judges would be free to reach opposite results in these cases, sometimes admitting the particular expert testimony and sometimes excluding it. This unjustifiable inconsistency not only denies fairness to the litigants, it

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[55] *See, e.g.*, Ruggiero J. Aldisert, *The Judicial Process* 753 (1976) ("guides to the exercise of discretion can easily crystallize into rules of law") (quoting Rupert Cross, *Precedent in English Law* 214-16 (2d ed. 1968)); Henry J. Friendly, *Indiscretion About Discretion*, 31 Emory L. Rev. 747, 772-73 (1982); *United States v. Criden*, 648 F.2d 814, 818 (3d Cir. 1981) ("although the selection of an appropriate remedy has been generally deemed to lie in the equitable discretion of the trial judge, after experience has accumulated the appellate courts may decide that a specific remedy should be awarded as a general rule.").

would strongly encourage forum shopping among the federal courts.[56]

As the Court of Appeals properly recognized here, "the answer to the question about the reliability of a scientific technique or process [should] not vary according to the circumstances of the case. It is therefore inappropriate to view this threshold question of reliability as a matter within each trial judge's individual discretion." J.A. 238-39 (internal quotation and citations omitted).

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

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January 19, 1993

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[56] Congress's adoption of the *Frye* rule does not present any concerns under *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938). Where, as here, there is a valid federal statute or federal rule of procedure on point, that is the end of the inquiry—the federal law controls. *Burlington Northern R. Co. v. Woods*, 480 U.S. 1, 5 (1987) (Federal Rule of Appellate Procedure on point).

APPENDIX

Alaska: *Contreras v. State*, 718 P.2d 129, 135 (Alaska 1986) ("The *Frye* standard is essentially a 'prejudice-versus-probative value test,' similar to Evidence Rule 403.").

Arizona: *State ex rel. Collins v. Superior Court*, 644 P.2d 1266, 1282 (Ariz. 1982), *overruled on other grounds, State v. Nuney*, 660 P.2d 858 (Ariz. 1983) ("*Frye* has been in use for almost 60 years without the development of any alternative as a *general* test of reliability. No such alternative has been seriously suggested in the case or in the literature, nor does any occur to this court." (emphasis in original)).

Hawaii: *State v. Montalbo*, 828 P.2d 1274, 1280-81 (Hawaii 1992) (adopted as part of a "reliability" analysis).

Iowa: *State v. Klindt*, 389 N.W.2d 670, 672-73 (Iowa 1986) indicates that general acceptance is still relevant, although the reliability of evidence may be "otherwise established" as well. *State v. Hall*, 297 N.W.2d 80, 83-85 (Iowa 1980), *cert. denied*, 450 U.S. 927 (1981).

Louisiana: *State v. Armstrong*, 561 So.2d 883, 886-87 (La. Ct. App. 1990) (applying *Frye*). *But see State v. Catanese*, 368 So.2d 975, 980 (La. 1979) (calling *Frye* an "unjustifiable obstacle"; decided before Uniform Rules of Evidence were adopted in Louisiana).

Michigan: *People v. Young*, 340 N.W.2d 805, 813 (Mich. 1983).

Minnesota: *State v. Jobe*, 486 N.W.2d 407, 419 (Minn. 1992).

Nebraska: *State v. Houser*, 490 N.W.2d 168, 178, 184 (Neb. 1992).

New Hampshire: *State v. Vandebogart*, No. 92-016, 1992 N.H. Lexis 181 at *19, *23 (N.H. Nov. 20, 1992).

North Carolina: *State v. Pennington*, 393 S.E.2d 847, 852-53 (N.C. 1990) (*Frye* is one indication of reliability).

Oklahoma: *Rawlings v. State*, 740 P.2d 153, 161 (Okla. Crim. App. 1987) (once the witness is qualified under a Rule 702 "helpfulness" inquiry, there must then be proof that "the reliability of the tests used has gained general acceptance and recognition in the concerned scientific community").

Rhode Island: *State v. Dery*, 545 A.2d 1014, 1016-17 (R.I. 1988) (relied upon *Frye* to exclude polygraph results). *But see State v. Wheeler*, 496 A.2d 1382, 1387-89 (R.I. 1985) (arguably rejecting *Frye*; case decided one year before Uniform Rules were adopted in Rhode Island).

South Dakota: *State v. Wimberly*, 467 N.W.2d 499, 505 (S.D. 1991).

Washington: *State v. Ortiz*, 831 P.2d 1060, 1069 (Wash. 1992) ("background theory or principle [must have] achieved general acceptance in the scientific community").

West Virginia: *State v. Woodall*, 385 S.E.2d 253, 259-60 (W.Va. 1989).

(21)

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In the Supreme Court of the United States

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WILLIAM DAUBERT AND JOYCE DAUBERT, Individually and as Guardians Ad Litem for Jason Daubert, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for Eric Schuller,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

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No. 92-102

In the Supreme Court of the United States

OCTOBER TERM, 1992

WILLIAM DAUBERT AND JOYCE DAUBERT, Individually and as Guardians Ad Litem for Jason Daubert, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for Eric Schuller,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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BRIEF OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

This brief is submitted in support of respondent, Merrell Dow Pharmaceuticals, Inc. ("Merrell"). By letters filed with the Clerk of the Court, petitioners and respondent have consented to the filing of this brief.

INTEREST OF AMICUS CURIAE

The Pharmaceutical Manufacturers Association ("PMA") is a voluntary, nonprofit association representing over 100 companies engaged in the discovery, development and marketing of prescription pharmaceutical products. PMA member companies produce the vast majority of prescription medicines used in the United States. They annually invest more than $8 billion in research and development, and this substantial private research effort is

the source of virtually all new medicines marketed in the United States. PMA member companies, together with the physicians who prescribe and the patients who use their products, have an important interest in making sure that the safety of these products is judged by techniques that are scientifically sound.

STATEMENT OF THE CASE

Bendectin—the product at issue in this case—is the only anti-nausea drug for pregnant women ever approved by the Food and Drug Administration ("FDA"). It was first sold in the United States in 1956, and during the next 27 years it was used in more than 33 million pregnancies. The FDA repeatedly reaffirmed its safety based on, among other things, scientific studies of this extensive actual usage. But respondent Merrell decided in 1983 to remove Bendectin from the market in the face of tort claims based on scientific opinion testimony of the kind rejected in this case.

The withdrawal of Bendectin from the market created what the American College of Obstetricians and Gynecologists called a "significant therapeutic gap."[1] Severe nausea during pregnancy is a serious condition for which Bendectin was the only effective therapy; since the withdrawal of Bendectin, the rate of hospitalization for this condition has doubled,[2] and the threat of pregnancy-related dehydration, acidosis, maternal nutritional deficiencies and

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[1] American College of Obstetricians and Gynecologists, *ACOG Statement on Bendectin* 1 (June 10, 1983).

[2] Steven H. Lamm, *et al.*, *Public Health Consequences of Not Prescribing Antiemetics for Nausea and Vomiting During Pregnancy* (abstract), Epidemic Intelligence Service, 38th Annual Conference (Centers for Disease Control, April 3-7, 1989). This has resulted in approximately $40 million in additional annual hospitalization costs. *Id.*

nerve damage—conditions that imperil the health of both mother and fetus—has increased.[3]

We argue in this brief that opening the door to scientific opinion testimony not grounded in principles and methodologies generally accepted in the relevant scientific community would be bad for the public's health as well as contrary to the Federal Rules of Evidence. We begin by describing the process by which the FDA, relying on the scientific community, determines the safety of medicines in general and determined that Bendectin in particular is safe and should be available to the women who need it.

A. Federal Law Requires That the Safety of Medicines Be Determined and Monitored in Accordance With Principles and Methodologies Generally Accepted by the Relevant Scientific Community

The Federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. §§ 301 *et seq.*, requires the FDA to determine the safety of a new medicine before allowing it to be sold, *id.* at § 355(d), and to monitor its safety continuously thereafter. *Id.* at § 355(e). This process is designed to rely on accepted scientific principles and methodologies and to bring to bear the views of the body of experts who comprise the relevant scientific community.

The FD&C Act requires the sponsor of a proposed new medicine to provide "adequate tests by all methods reasonably applicable" to show that the medicine is safe. 21 U.S.C. § 355. FDA regulations implementing this provision require an application containing a summary

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[3] Andrew Skolnick, *Key Witness Against Morning Sickness Drug Faces Scientific Fraud Charges*, 263 J. AM. MED. ASSOC. 1468, 1473 (1990).

"written at approximately the level of detail required for publication in . . . refereed scientific and medical journals." 21 C.F.R. § 314.50(c)(1) (1992). The application itself must contain elaborately prescribed chemical, biological, pharmacological, clinical, statistical, and case-report information, which must be set forth "in sufficient detail to permit the agency to make a knowledgeable judgment." *Id.* at § 314.50(d). The regulations explicitly require information that will enable scientific reviewers to evaluate the data supplied, such as a "description of the analytical and statistical methods used in each [bioavailability or pharmacokinetic] study," *id.* at § 314.50(d)(3)(i), and "the protocol and a description of the statistical analyses used to evaluate" each chemical study, *id.* at § 314.50(d)(5)(ii). In accordance with good scientific practice, information must also be provided about any unanalyzed or discontinued studies. *Id.* The flow of information continues after marketing of a drug begins. *See id.* at §§ 314.80-81.[4]

Even more importantly, the essence of the FDA's examination of data submitted and other information bearing on drug safety is critical evaluation by scientific experts applying accepted principles and methodologies. The FDA itself, of course, employs scientists trained in the

[4] In addition to requiring "adequate tests" of safety, the FD&C Act requires "adequate and well controlled investigations" of effectiveness. 21 U.S.C. § 355(d). A good indication of the kind of scientific information the FDA requires is its extremely elaborate definition of this term, including specific requirements concerning controls, methods of selection of subjects, methods of assigning patients to treatment and control groups, measures to minimize bias on the part of subjects, obeervers and analysts, and an instruction to follow "well defined and reliable" methods of assessment of subjects' responses. *Id.* at § 314.126(b) (1992). *See also* Department of Health and Human Services, *Guidelines Applicable to the Center for Drug Evaluation and Research's Regulations* (undated).

various relevant scientific disciplines[5] who work together to evaluate new drug applications[6] and monitor drug performance after marketing begins.[7] But in order to assure that the principles and methodologies applied by its own scientists are accepted by the relevant scientific community, the FDA backs them up with seventeen standing advisory committees of scientific professionals who are experts on matters relating to drugs and biologics. "[A]dvisory committees offer FDA staff a dialogue with the nation's foremost experts in drug therapy. The committees are thus an important source of peer review for proposed FDA decisions."[8] Although the FDA is not legally bound to follow the recommendations of its advisory committees, *see* 21 C.F.R. § 14.5 (1992), it usually does, and the use of advisory committees has been

[5] There are several groups of such scientists, including chemists (to examine a medicine's chemical properties); pharmacologists (to evaluate effects on laboratory animals); physicians (to evaluate clinical tests); statisticians (to evaluate the design, validity, and conclusions of controlled studies and statistical analyses); and other experts who evaluate how a drug's active ingredients are distributed, metabolized and eliminated. *See* Dixie Farley, *How FDA Approves New Drugs*, *in* FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES 29 (Food and Drug Administration, 1990 rev. ed.).

[6] *See id.*; Department of Health, Education and Welfare, *Final Report: Review Panel on New Drug Regulation* 21 (1977) [hereinafter "*HEW Final Report*"].

[7] Stephen J. Ackerman, *Watching for Problems That Testing May Have Missed*, *in* FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES 49 (Food and Drug Administration, 1990 rev. ed.); *HEW Final Report* at 92-93.

[8] *HEW Final Report* at 52. *See also* 21 C.F.R. § 14.160(b)(2) (1992) (in the case of human prescription drugs, FDA relies on advisory committees to advise it as to whether a "particular drug meets the statutory standard for proof of safety and effectiveness necessary for approval or continued approval for marketing"); Food and Drug Administration, *FDA Public Advisory Groups: Authority, Structure, Functions, Members* iii (1990).

much encouraged.[9] FDA advisory committees play a particularly significant role in cases where the FDA has been presented with evidence suggesting that a drug being marketed is not safe. *See* 21 C.F.R. § 14.171(b)(2) (1992).[10]

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[9] The present FDA Commissioner, Dr. David Kessler, had once criticized the agency for acting on isolated evidence not evaluated by the relevant scientific community. *See* David A. Kessler, *Food Safety: Revising the Statute*, 223 SCIENCE 1034, 1039 (1984). The case involved a plan to ban the use of nitrites as a food additive on the basis of a single study finding that nitrites caused an increased incidence of lymphatic cancer in certain laboratory animals. Subsequent peer review of the study showed that its author had misinterpreted the data and that there was no basis for the conclusion that nitrites cause cancer. *See* U.S. Congress, House Committee on Agriculture, Hearings on USDA-FDA Announcement on Nitrites and Related Issues, 96th Cong., 2d Sess. (1980). According to Kessler, "[t]his incident clearly demonstrated the need for independent scientific review of important food safety studies." Kessler at 1039.

[10] The FD&C Act itself provides that whether a drug is "new," and thus needs premarketing approval, depends on the view of the relevant scientific community. A drug is not "new" if it is "generally recognized, among experts qualified by scientific training and expertise to evaluate the safety and effectiveness of drugs, as safe and effective for use." 21 U.S.C. § 321(p)(1) (1988). As this Court explained in *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 652 (1973), "[w]hether a particular drug is a 'new drug,' depends in part on the expert knowledge and experience of scientists based on controlled clinical experimentation and backed by substantial support in scientific literature."

The FDA places similar reliance on the views of relevant scientific communities in other areas of its work. FDA determinations of whether a food additive is "generally recognized as safe," and therefore does not need pre-marketing approval, rely on "common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food," 21 C.F.R. § 170.30(a) (1992); the determination is ordinarily based on published studies, *id.* at § 170.30(b). And FDA evaluations of the truth of health claims for foods require a

B. The Safety of Bendectin Has Been Established in Accordance with Principles and Methodologies Generally Accepted by the Relevant Scientific Community

The role of the scientific community in evaluating the safety of a medicine is well illustrated by the FDA's extensive review of the safety of Bendectin. Bendectin was first approved as safe by the FDA and marketed in 1956.[11] The FDA continued to monitor the drug's safety throughout the 1960's and 70's. In 1979, the FDA summarized its review of Bendectin up to that point, finding "no evidence" associating the drug with birth defects.[12] The next year, the FDA asked its Fertility and

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determination "that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims." 21 U.S.C.A. § 343(r)(3)(B)(i) (1990). Such scientific agreement must include "evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles." *Id.*

[11] C.I. Barash & Louis Lasagna, *The Bendectin Saga: "Voluntary" Discontinuation*, 1 J. CLIN. RES. DRUG. DEV. 277, 282 (1982); Food and Drug Administration, Fertility and Maternal Health Drugs Advisory Committee, 2 *Proceedings of Meeting on Bendectin* 8 (Sept. 15-16, 1980) [hereinafter *"Bendectin Proceedings"*].

[12] Food and Drug Administration, *Talk Paper: Bendectin* 1-2 (Oct. 1, 1979):

> Because of the extensive use of this drug, FDA over the years has carefully monitored it, with a particular view to its effect on the fetus. In the studies to date, there is no evidence that Bendectin is associated with an increased risk of birth defects. Tests have been conducted in rats and rabbits in which doses up to 100 times the maximum human dose were given; no association was reported. Also reviewed by FDA have been several large epidemiological studies in women who received the drug

Maternal Health Drugs Advisory Committee to review the scientific data on the issue.[13] The Committee heard more than thirty witnesses, including experts in the fields of pharmacology, epidemiology, obstetrics, gynecology and pediatrics, and reviewed eight major human epidemiological studies, five major case control studies (*i.e.*, studies in which subjects are selected in accordance with their disease status and investigated to determine their prior histories of exposure), and over twenty years of animal studies. Food and Drug Administration, *Bendectin Proceedings*. On the basis of all the existing data, the Committee concluded that no "association between the drug and an increased risk of human birth defects" had been demonstrated.[14] The FDA revisited the question of Bendectin's safety in 1982-83. A 34-page report prepared by its Center for Drugs and Biologics reviewed the history of Bendectin, examined human and animal studies of Bendectin and its individual components, and concluded that the "available information [does not] support[] a conclusion that Bendectin is teratogenic in humans."[15]

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during pregnancy.

The circumstances leading to this statement are described in Skolnick, *supra* note 3, at 1469.

[13] *See* Meeting Notices, 45 Fed. Reg. 49682 (1980); 45 Fed. Reg. 51921 (1980); 45 Fed. Reg. 58966 (1980).

[14] 45 Fed. Reg. 80740, 80741 (1980). The Committee did note a "residual uncertainty" in the sensitivity of several of the available studies and recommended that certain current epidemiological studies of Bendectin be continued and that certain changes be made in the drug's labeling. *Id.* The FDA later explained that the "'residual uncertainty' existed in spite of the largely negative human experience since it is not possible to prove unequivocally that a drug could never cause birth defects." Food and Drug Administration, *Talk Paper: Bendectin* 1 (June 29, 1982).

[15] Food and Drug Administration, National Center for Drugs and Biologics, *Report in Response to Questions Contained in Congressman*

SUMMARY OF ARGUMENT

Opening the door to scientific opinion testimony not grounded in principles or methodologies generally accepted by the scientific community would be bad for the public's health as well as contrary to the Federal Rules of Evidence.

1. There is an important public health interest in the availability of medicines that have been shown to be

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Walgren's May 6, 1982 Letter on Bendectin 34 (Feb. 23, 1983). The national health agencies of at least six other countries (Canada, Australia, Germany, Great Britain, Ireland and Switzerland), as well as the World Health Organization, have reached the same conclusion—namely, that the evidence does not support the view that Bendectin is a teratogen. *See* Special Advisory Committee on Reproductive Physiology (Canada), *Report on the Safety of Bendectin/Diclectin for Use in the Management of Nausea and Vomiting in Pregnancy* (Aug. 11, 1989), Joint Appendix ("JA") 212 [hereinafter *"Canadian Report"*]; Australian Drug Evaluation Committee, *Debendox in Pregnancy*, 53 MED. J. AUSTRALIA 197 (1980). ("Sub-committee does not consider that the use of Debendox [Bendectin] in pregnancy has been shown to increase the risk of birth defects."); Bundesgesundheitsamt (Germany), *Statement Concerning the Antiemeticum Lenotan* (June 1980); National Drugs Advisory Board (Ireland), *Final Statement* (May 13, 1980); Statement of Sir George Young, Under-Secretary of State for Health and Social Security, in address to Parliament (Great Britain), 984 PARL. DEB., H.C. (5th Ser.) 672-73 (1980) ("[W]e probably know more about this drug than any other which might be used for vomiting in pregnancy, and what we know is reassuring—that is, that all the research that has been carried out suggests that a woman who takes Debendox [Bendectin] is no more likely to put her unborn child at risk than a mother who does not."); Interkantonale Kontrollstelle Für Heilmittel ("IKS") (Switzerland), *Lenotan/Antinausea Drug During Early Stage Pregnancy* (Feb. 8, 1980); World Health Organization, *Drug Information Bulletin* (Oct.-Dec. 1979) ("[M]ore than 20 million women are known to have used [Bendectin and related drugs] since 1956. Neither experimental studies nor epidemiological investigations have yielded evidence to justify concern [about an alleged association with congenital malformations].").

safe and effective. For example, Bendectin filled a significant therapeutic gap: it was the only available drug therapy for serious nausea and vomiting experienced by many women during pregnancy; such a therapy is needed to combat a sometimes serious threat to the nourishment of both mother and fetus.

The availability of safe and effective drugs depends not only on the successful functioning of the regulatory scheme administered by the FDA but also on the proper operation of the tort system. Whether a given drug has a particular effect is generally a scientific question, and while "science" is not a fixed body of knowledge, there are principles and methodologies that are generally accepted by scientific communities; there are also sincerely held individual opinions, based on idiosyncratic views or poorly conducted studies, to which other scientists themselves accord no weight. The FDA regulatory scheme is designed to bring sound science to bear on questions of drug safety. If the tort system were opened up to allow lay juries to hear and rely on scientific opinions not grounded in generally accepted principles and methodologies—opinions that the relevant scientific community itself would not rely on—the result would be to discourage both the marketing of, and research toward, safe and effective medicines important for the public's health.

The case of Bendectin is a good example. Federal courts applying the Rules of Evidence have in almost every case ultimately rejected claims that Bendectin is a teratogen. But even the threat of claims based on evidence like that proffered in this case was sufficient: Bendectin is not available today because "the manufacturer . . . found the legal costs of defending its use (successfully in the majority of cases) to be prohibitive." *Canadian Report*, JA at 215.

2. The Federal Rules of Evidence require the exclusion of scientific opinions not grounded in generally

accepted principles and methodologies. While there are many sources of support for this conclusion, our argument is based squarely on the text of the pertinent Rules.

Rule 102 provides that the Rules are to be "construed to secure . . . promotion of growth and development of the law of evidence to the end that the truth may be obtained." It thus explicitly instructs the courts to construe the terms of the other Rules to provide a foundation for a body of evidence law that will assist the search for truth.

Rule 702 permits expert testimony as to scientific "knowledge" that will "assist the trier of fact." The witness may testify only "thereto." The plain meaning of scientific "knowledge" is matters the relevant scientific community "knows." Opinions not grounded in such knowledge do not "assist the trier of fact" to reach the truth.

Rule 703 allows the expert to base his opinion on unproven "facts or data . . . . of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject . . . ." The plain meaning of this Rule is that where (as in virtually every case of this kind) the testimony is based on scientific work not in evidence, the court must determine whether the relevant community of scientists would rely on that work. Petitioners' argument that this Rule relates only to bits of information and not, for example, to the method of determining which bits are relevant, is contrary to the text and thrust of the Rule as well as the search for truth.

The opinion testimony at issue in this case, which was based on the witnesses' reanalyses of epidemiological data, was properly rejected. An expert seeking support for a desired conclusion can all too easily find that support through plausible retrospective adjustments to the numerators and denominators of past statistical studies. When he does so but neither submits his adjustments to review by other scientists, nor otherwise demonstrates that

his work would be relied on by other scientists, his opinion does not assist the search for truth.

ARGUMENT

I. THE PUBLIC INTEREST IN THE AVAILABILITY OF SAFE AND EFFECTIVE MEDICINES WOULD BE SERIOUSLY DISSERVED IF THIS COURT WERE TO OPEN THE DOOR TO SCIENTIFIC OPINION TESTIMONY NOT GROUNDED IN PRINCIPLES AND METHODOLOGIES GENERALLY ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY.

One aim of tort law is to deter harmful conduct.[16] By imposing liability on the manufacturer of an unsafe product, society discourages its manufacture and sale.[17] But the deterrent effect is not automatically limited to products that actually cause injury. If there is a threat that unsound scientific opinion evidence will lead juries to award damages in cases where the asserted causal link is false, that threat will just as surely discourage the production of safe and beneficial products. If the door to such evidence were opened in cases involving prescription drugs, the result would be to deny the public safe, life-saving and health-preserving medicines.

Whether a given medicine has a particular effect is generally a scientific question and often a complex one. That is, the question can be answered truthfully only after the application of one or several scientific tests and analyses. As we have outlined above, when the FDA examines such questions, it seeks to bring to bear

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[16] *E.g.*, *Owen v. City of Independence*, 445 U.S. 622, 651 (1980).

[17] *See* Guido Calabresi, *Optimal Deterrence and Accidents*, 84 Yale L.J. 656 (1975).

principles and methodologies generally accepted by the relevant scientific community.

But the FDA is not the only body whose views determine whether a drug will be marketed. If a lay jury finds that a drug caused a plaintiff's tragic injury, that finding may well curtail the manufacture and marketing of the drug. If the jury makes such a finding based on an erroneous scientific opinion as to causation, the result may be not only to deny the public a safe and beneficial medicine but to discourage research in related areas. Since the jury (unlike the FDA) does not have available to it a trained and neutral scientific staff and neutral advisory bodies composed of leading experts in the relevant fields, it is of immense practical importance that the Federal Rules of Evidence require that, before a proffered scientific opinion is admitted into evidence, the court determine that it is grounded in generally accepted principles and methodologies. Were this Court now to open the door, as petitioners ask, to the admission of any opinion expressed by a witness who can qualify as an expert, the adverse consequences to the public health would be very serious.

Petitioners argue (Br. 47) that because "scientific knowledge" is not a fixed body of truths, there is no basis for admitting one proffered expert opinion and excluding another.[18] But there is no reason for the Court to open the

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[18] Petitioners and certain amici also argue that restricting scientific opinion testimony to opinions grounded in generally accepted principles and methodologies restricts scientific research and may thwart recognition of an as-yet-unheralded Pasteur or Galileo. But this case has nothing to do with the right of a working scientist to speculate or disagree with his colleagues: the issue is whether the scientific evidence on which *juries* are allowed to rely should be limited to evidence on which the court finds *other scientists* would rely. And this case does not remotely involve "cutting edge" science. *See DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 791 F. Supp. 1042 (D.N.J. 1992) (lengthy analysis of the proffered testimony of two principal witnesses in *this* case, showing it to be based on a hodgepodge of unexplained,

door to permit juries to rely on scientific opinions that the relevant scientific community would not rely on. And scientific communities *do* have a way to judge any given piece of scientific work at a given time: general acceptance. "Scientific truths" are those about which "informed observers can agree."[19] "The collective judgment of scientists, in so far as there is substantial agreement, constitutes the body of science. The fact that there are very large areas of agreement, in spite of the individualistic, antiauthoritarian nature of science, is partial evidence for the validity of scientific methods."[20] And scientists *do* have generally accepted standards for evaluating the research support for specific conclusions, including the use of controls, the replicability of results, statistical analyses of possible error, and peer review through publication.[21]

The threat that safe and valuable products will be lost and important research will be discouraged is quite real. It has manifested itself even in an era in which the courts have applied the Federal Rules of Evidence to exclude scientific opinions not grounded in generally accepted principles and methodologies, making litigation like this case generally unsuccessful.

Bendectin is a perfect example. The drug is demonstrably beneficial to both mother and child in cases of severe morning sickness, and its safety has repeatedly been confirmed by the FDA. Nevertheless, because

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improperly selected, misrecorded, and mischaracterized data, assembled for purposes of litigation rather than research).

[19] Warren O. Hagstrom, THE SCIENTIFIC COMMUNITY 273 (1965).

[20] E. Bright Wilson, Jr., AN INTRODUCTION TO SCIENTIFIC RESEARCH 21 (3d ed. 1990).

[21] *See, e.g., id.* at 36-48; Mario Bunge, SCIENTIFIC RESEARCH (1967); William G. Cochran & Gertrude M. Cox, EXPERIMENTAL DESIGNS (1950).

unexplained birth defects are a constant of human experience and the use of Bendectin was very widespread, almost 1700 suits were brought against Merrell alleging that Bendectin caused such defects.[22] On the critical question of causation of injury, every plaintiff depended on scientific testimony not grounded in generally accepted principles and methodologies. But even though federal courts have broadly rejected reliance on such testimony, the costs of the litigation led Merrell in June 1983 to withdraw Bendectin from the market.[23] Thoughtful commentators blamed the loss of Bendectin squarely on the threat of litigation that, as exemplified by the decision under review, has been overwhelmingly unsuccessful.[24]

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[22] *See* Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HAST. L. REV. 301, 319 (1992).

[23] *See Canadian Report*, JA 215 (Bendectin withdrawn from market because legal costs of defending its use were "prohibitive"); *ACOG Statement on Bendectin, supra* note 1, at 1; Peter Huber, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM 127 (1991); Skolnick, *supra* note 3, at 1469; Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development* 338, 340 *in* THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION (Peter W. Huber & Robert E. Litan, eds., 1991).

[24] *See, e.g.*, J. Steven Leeder, *et al.*, *Editorial: The Wrong Way to Regulate Drug Availability*, 129 CAN. MED. ASSOC. J. 1085, 1087 (1983):

> The decision about which drug to use should be based on results of studies with the widest patient exposure and the best possible data that show no increased risk of birth defects. The availability of drugs should not be regulated by the media, litigation lawyers or public hysteria but should continue to be a result of careful examination of scientific evidence . . . . The net result [of the burden placed on the pharmaceutical manufacturer by litigation] is that a product well studied for use in pregnancy will no longer be available to patients requiring antiemetic medication. This will force physicians to prescribe, and pregnant women to take, medications for which we lack

The diphtheria-tetanus-pertussis ("DTP") vaccine provides a different example. Pertussis (also known as "whooping cough") was once a major cause of childhood morbidity and mortality.[25] The introduction of pertussis vaccines in the late 1940's led to a substantial decline in the disease that continued for thirty years. *Id.* In the 1950's and 1960's, however, there began to be anecdotal reports that the pertussis component of the vaccine caused sudden infant death syndrome ("SIDS") and other adverse neurological reactions. The FDA and the broader scientific community conducted investigations to determine whether there is a causal connection between the vaccine and these adverse reactions. In 1979-81, for example, the FDA sponsored a major study, carried out at UCLA,[26] which failed to find any correlation between DTP vaccine and

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> the large amount of reassuring data on teratogenicity that we have for Bendectin.

See also Robert L. Brent, *Editorial: The Bendectin Saga: Another American Tragedy*, 27 TERATOLOGY 283, 284 (1983):

> If the FDA and the epidemiological studies do not indicate that Bendectin is a teratogen, upon what are the lawsuits based? They are based on the ability to obtain expert witnesses who are willing to testify "with a reasonable degree of medical certainty" that Bendectin caused a particular malformation in a child and the incentive for an attorney of obtaining a large award for his client and himself.

[25] At its peak in 1922, there were 265,269 reported cases of pertussis and 9,269 deaths. Immunization Practices Advisory Committee, Centers for Disease Control, *Diphtheria, Tetanus, and Pertussis: Recommendations for Vaccine Use and Other Preventive Measures*, 40 MMWR 1, 3 (1991).

[26] *See* Institute of Medicine, ADVERSE EFFECTS OF PERTUSSIS AND RUBELLA VACCINES 323 (1991).

SIDS or long-term neurological disorders.[27] Subsequent studies have confirmed these findings, and there is now an all but unanimous consensus of the interested governmental and professional bodies that no causal relationship between the DTP vaccine and SIDS or long-term neurological disorders has been established.[28]

Despite the consensus, many product liability suits (based on the testimony of a small group of "experts" who regularly testify on behalf of personal injury claimants) alleging that DTP vaccine caused SIDS and other long-term neurological deficits were filed. Between 1960 and 1985 litigation costs drove seven of the eight manufacturers to withdraw their DTP vaccines from the market.[29] Were the remaining manufacturer to follow them, the nation would be faced with a health crisis of major proportions.[30]

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[27] *See* C.L. Cody, *et al.*, *Nature and Rates of Adverse Reactions Associated with DTP and DT Immunizations in Infants and Children*, 68 PEDIATRICS 650 (1981). The study did find a correlation between the vaccine and higher rates of "minor and short-term reactions." *Id.* at 658.

[28] *See* Institute of Medicine, *supra* note 26, at 118 & n.3; Immunization Practices Advisory Committee, *supra* note 25, at 10-11; Ad Hoc Committee for the Child Neurology Society Consensus Statement on Pertussis Immunization and the Central Nervous System, *Consensus Statement: Pertussis Immunization and the Central Nervous System*, 29 ANNALS OF NEUROLOGY 458, 458-59 (1991); Committee on Infectious Diseases, American Academy of Pediatrics, *The Relationship Between Pertussis Vaccine and Brain Damage: Reassessment*, 88 PEDIATRICS 397, 399 (1991); Therapeutics and Technology Assessment Subcommittee, American Academy of Neurology, *Assessment: DTP Vaccination*, 42 NEUROLOGY 471, 471 (1992).

[29] *See* Robert M. McKenna, *The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus*, 55 U. CHI. L. REV. 943, 955 (1988); *see also* Lasagna, *supra* note 23, at 342-43.

[30] *See* Alan R. Hinmon & Jeffrey P. Koplan, *Pertussis and Pertussis Vaccine: Reanalysis of Benefits, Risks, and Costs*, 251 J. AM.

The same threat has discouraged pharmaceutical manufacturers from conducting research into new products, particularly in areas where unexplainable tragedies can be expected to occur, such as obstetrics and fertility technology.[31]

In sum, Congress and the FDA have created an elaborate mechanism for regulating the sale of medicines. Through that process, principles and methodologies that are generally accepted in the scientific community are brought to bear on regulatory decisions about whether a medicine is safe enough to be marketed. If this Court were now to accept petitioners' invitation to open the door to scientific testimony not grounded in such principles and methodologies, the result would be to deprive the public of important medicines to combat sickness, pain and death.

MED. ASSOC. 3104, 3112 (1984) (if the vaccine were not administered, there would be approximately 350,000 cases of pertussis annually and approximately 457 deaths).

In 1986, Congress enacted the National Vaccine Compensation Act, 42 U.S.C. §§ 300aa-1 *et seq.*, establishing a fund to pay compensation for vaccine-related injury or death. The Act has not put an end to the possibility of DTP tort suits, however, because it does not apply to cases in which the vaccine was administered after September 30, 1992, *see* H.R. No. 4210, 102d Cong., 2d Sess., at 405 (1992) (Conference Report, Tax Fairness and Economic Growth Act of 1992), or in which plaintiffs fail to file within the statutorily required time period, 42 U.S.C. § 300aa-16 (1988). *See, e.g., Pease v. American Cyanamid*, 795 F. Supp. 755, 758 (D. Md. 1992) (DTP suit based on "scant" scientific data).

[31] *See, e.g.*, American Medical Association, *Impact of Product Liability on the Development of New Medical Technologies* (June 1988); Skolnick, *supra* note 3, at 1473; *see also* President's Council on Competitiveness, *Agenda for Civil Justice Reform in America* 3 (1991) (Conference Board study reported that fear of potential liability has resulted in 25 percent of U.S. manufacturers having discontinued some form of product research).

As we now show, the Federal Rules of Evidence bar such a result.

II. THE FEDERAL RULES OF EVIDENCE REQUIRE THE DISTRICT COURTS TO EXCLUDE SCIENTIFIC OPINION TESTIMONY NOT GROUNDED IN PRINCIPLES AND METHODOLOGIES GENERALLY ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY.

The issue in this case is not, as petitioners claim, whether the rule of *Frye v. United States*, 293 Fed. 1013 (D.C. Cir. 1923), "survived" the adoption of the Federal Rules of Evidence. The issue is whether Federal Rules require the exclusion of scientific testimony not grounded in principles and methodologies generally accepted by the relevant scientific community.[32] Our argument that they do rests on the text of the Rules.

Rule 102 states as follows:

> *Purpose and Construction.* These rules shall be construed to secure fairness in administration, elimination of unjustifiable expense and delay, and promotion of growth and development of the law of evidence to the end that the truth may be ascertained and proceedings justly determined.

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[32] It is surely relevant that such a requirement, as articulated in *Frye*, was widely accepted by the federal courts as part of the law of evidence at the time the Rules were adopted, *see United States v. Downing*, 753 F.2d 1224, 1234 (3rd Cir. 1985), and was nowhere rejected by the drafters of the Federal Rules. As this Court concluded on a similar question, *see United States v. Abel*, 469 U.S. 45, 50 (1984), it is unlikely that the drafters of the Rules intended, *sub silentio*, to scuttle a widely accepted evidentiary principle.

This text instructs the federal courts that the necessarily general provisions of the Rules are to serve as a foundation for the "growth and development of the law of evidence,"[33] and that the Rules are to be construed to achieve a purpose with which the courts have special familiarity: "that the truth may be ascertained" in court proceedings.[34] Rule 102 also makes it clear that the text of one Rule may bear on the meaning of another. As the Reporter said, the Rules "must not be read separately and in isolation but as a part of an entire system, with due regard to its plan and organization and to the contents of rules other than the particular one under consideration."[35] In sum, there is an explicit statutory instruction that the Rules that bear directly on this case, Rules 702, 703 and 403, are to be read together in light of their truth-seeking purpose.

Rule 702. Rule 702 states in part that if "scientific . . . *knowledge* will assist the trier of fact to . . . determine a fact in issue . . . an expert . . . may testify *thereto*." (Emphasis added.) As lower courts have

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[33] *See* Edward W. Cleary, Reporter for the Federal Rules of Evidence, *Preliminary Notes on Reading the Rules of Evidence*, 57 NEB. L. REV. 908, 912 (1978) (Rule 102 indicates that "all answers are not to be found in specific terms in the Rules"); Michael H. Graham, HANDBOOK OF FEDERAL EVIDENCE § 102.1 at 2 (3d ed. 1991) (Rule 102 negates the common law rule that statutes and rules in derogation of common law are to be strictly construed), *citing* James W. Moore, 2 MOORE'S FEDERAL PRACTICE § 1.13[1] at 1-60 (2d ed. 1989).

[34] Some courts have gone even further. *See United States v. Metzger*, 778 F.2d 1195, 1201 (6th Cir. 1985) ("[A]t times 'the technical requirements of [the] rules must bend in order to fulfill the objectives expressed in Rule 102,'" quoting Jack B. Weinstein & Margaret A. Berger, 1 WEINSTEIN'S EVIDENCE ¶ 102[01] at 102-7 (1985)), *cert. denied*, 477 U.S. 906 (1986).

[35] Cleary, *supra* note 33, at 917. *See Huddleston v. United States*, 485 U.S. 681, 687 (1988) (reading Article IV rules together).

recognized, the plain meaning of these words is that an expert may express an opinion based on what the relevant scientific community "knows." "[A]n expert is a conduit of facts and not merely a subjective speculator relying on stature alone."[36] The district court must make a preliminary inquiry under Rule 702 to "determine on the basis of evidence or by judicial notice that the subject matter of the expert's testimony is one as to which a reliable body of *scientific . . . knowledge* has been developed."[37] The textual limitation to "scientific . . . knowledge" applies both to general propositions of science asserted by a witness (*e.g.*, Bendectin causes birth defects) and to techniques and methodologies (*e.g.*, reanalysis of epidemiological evidence) that form the basis for the witness's testimony.

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[36] *Porter v. Whitehall Lab., Inc.*, 791 F. Supp. 1335, 1343 (S.D. Ind. 1992) (citing *American Nat'l Bank & Trust Co. v. K-Mart Corp.*, 717 F.2d 394, 399 (7th Cir. 1983)). *See also Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 422 (5th Cir. 1987).

[37] Graham, *supra* note 33, § 702.4 (emphasis added); *see In re "Agent Orange" Prod. Liab. Litig.*, 611 F. Supp. 1223, 1241-42 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987); *cf. Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 829 (D.C. Cir. 1988) ("[a court need not] accept uncritically any sort of opinion espoused by an expert merely because his credentials render him qualified to testify"), *cert. denied*, 483 U.S. 882 (1989).

Especially careful evaluation of scientific testimony is needed because the expert "assumes a posture of mystic infallibility in the eyes of a jury of laymen." *United States v. Addison*, 498 F.2d 741, 744 (D.C. Cir. 1974). Moreover, "close judicial analysis of such technical and specialized matter is necessary not only because of the likelihood of juror misunderstanding, but also because expert witnesses are not necessarily always unbiased scientists." *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1352 (6th Cir.), *cert. denied*, 113 S. Ct. 84 (1992). For these reasons, judges should "take hold of expert testimony in federal trials," especially when the expert testimony goes to a decisive substantive issue. *In re Air Crash Disaster at New Orleans, La.*, 795 F.2d 1230, 1233-34 (5th Cir. 1986).

By allowing testimony only as to "scientific . . . knowledge," the Rule instructs the courts to determine whether the principles and methodologies on which the testimony is based are accepted by "those most qualified to assess the general validity of a scientific method,"[38] *i.e.*, the relevant scientific community. As we showed at pages 13-14, *supra*, "scientific knowledge" is a meaningful and important concept even though the content of science is not fixed or immutable: it refers to propositions that the relevant scientific community would find reliable.

Scientific opinion testimony is limited to "scientific knowledge" because the explicit purpose is to "assist the trier of fact to understand the evidence or to determine a fact in issue." A scientific opinion that "lacks the foundation and reliability necessary to support expert testimony . . . does not serve the purposes for which it is offered, that is, objectively to assist the jury in arriving at its verdict." *Viterbo v. Dow Chemical Co.*, 826 F.2d 420, 424 (5th Cir. 1987). *See Sterling v. Velsicol*, 855 F.2d 1188, 1208 (6th Cir. 1988) (under Rule 702, in order to prevent jury deception or mistake, expert testimony must conform to generally accepted explanatory theory). It does not "assist the trier of fact" to determine the truth in a scientific controversy to allow that trier to rely on opinions that the scientific community would not rely on.

Rule 703. Rule 703 provides that if scientific testimony is based on facts or data not in evidence, the facts or data must be "of a type reasonably relied upon by experts in the particular field in forming . . . inferences upon the subject." In this case, as in most, the scientific witnesses relied substantially upon facts or data not in evidence: for example, plaintiffs' experts relied on their "reanalysis" of epidemiological studies. Plainly, most experts in the particular field would *not* rely on the "facts

[38] *Addison*, 498 F.2d at 743-44.

or data" relied on by these witnesses to conclude that Bendectin causes birth defects: the original studies led the scientific community to the opposite conclusion, and the reanalyses were not submitted for review by any other scientists, and the courts below were offered no basis to conclude that other scientists would rely upon them.

Petitioners argue (Br. 37) that "facts or data" refers only to bits of empirical information and not to any methodological aspect of a scientific study. But that argument is plainly wrong: as the circuits that have addressed the issue have held, the Rule makes no sense unless "facts or data" is construed to mean the entirety of any scientific study on which the proffered opinion is based.[39]

The bits of data in a scientific study are the result of rules of selection. It is simply meaningless to ask whether the bits of data, standing alone, would be "reasonably relied upon by experts" in the particular field: that

[39] "[C]ourts must critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to consistently and rationally resolve the disputes before them." *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 310, *modified*, 884 F.2d 166, *reh'g denied, en banc*, 884 F.2d 167 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990).

In addition to *Brock* and the 9th Circuit's decision in this case, decisions applying Rule 703 to methodology include: *Lynch v. Merrell-Nat'l Lab.*, 830 F.2d 1190, 1195 (1st Cir. 1987) (reanalysis methodology rejected); *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1115 (5th Cir. 1991) (courts must analyze validity of methodology by determining whether it connects facts to conclusions in scientifically valid way), *cert. denied*, 112 S. Ct. 1280 (1992); *United States v. Tranowski*, 659 F.2d 750, 756 (7th Cir. 1981) (accuracy of methodology for dating photographs by reference to position of sun not established); *Head v. Lithonia Corp.*, 881 F.2d 941, 943 (10th Cir. 1989) (expert must rely on methods that other experts in the field would rely on); *Richardson*, 857 F.2d at 831 (reanalysis methodology rejected).

depends on how they were selected and how they are analyzed.[40] For example, the fact that specified persons took a medicine, and that certain of them did and others did not experience a specified condition at some point thereafter, could not be relied on by any expert to prove anything. Those bits of data are meaningful only in conjunction with other facts that determine whether the specified persons are a proper sample of a relevant population, whether they have been compared with a properly selected control group, and similar matters. Without analyzing these other facts, one cannot tell whether the bits of data about individual patients would be "reasonably relied upon by experts in the particular field" in reaching the conclusion proffered.[41]

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[40] Many would argue that "data" and "methodology" cannot be separated at all:

> [I]n almost every act of our perceiving faculties, observation and inference are intimately blended. What we are said to observe is usually a compound result, of which one-tenth may be observation, and the remaining nine-tenths inference.

John Stuart Mill, 2 SYSTEM OF LOGIC 186 (5th ed. 1872) (quoted in Leonard K. Nash, THE NATURE OF THE NATURAL SCIENCES 11 (1953)).

[41] Petitioners argue (Br. 36) that Rule 703's only effect is to open the door to additional testimony, but the Advisory Committee's Note makes it clear that the Rule's language was intended to be restrictive: "If it be feared that enlargement of permissible data may tend to break down the rules of exclusion unduly, notice should be taken that the rule requires that the facts or data 'be of a type reasonably relied upon by experts in the particular field.'" FED. R. EVID. 703 Advisory Committee's note ¶ 3. Another expert has noted that the rule invites judicial scrutiny of the trustworthiness of the facts, data or opinions by its express reference to information that experts "reasonably" rely upon. *See* Graham, *supra* note 33, § 703.1 at 638, n.13.

Indeed, the Advisory Committee's comment on Rule 703 offers as an example of the operation of the Rule the use of public opinion poll evidence, where the issue is "the validity of the technique employed." The Committee cites with approval Judge Feinberg's opinion in *Zippo Manufacturing Co. v. Rogers Imports, Inc.*, 216 F. Supp. 670 (S.D.N.Y. 1963), admitting a public opinion survey on the ground that "the methodology of the survey" established its "trustworthiness." *Id.* at 684. *See also Toys "R" Us, Inc. v. Canarsie Kiddie Shop, Inc.*, 559 F. Supp. 1189, 1205 (E.D.N.Y. 1983) (public opinion survey data must be analyzed in accordance with "accepted statistical principles").

Rule 403. The principles that underlie Rule 403 reinforce the lower courts' interpretation of Rules 702 and 703. Rule 403 expressly authorizes a district judge to weigh the "probative value" of expert testimony and other evidence against "the danger of unfair prejudice, confusion of the issues, or misleading the jury."

As the district court recognized, JA 229, Rule 403 typically will not come into play directly, because scientific evidence whose probative value is substantially outweighed by the likelihood of confusing or misleading the jury will already have been screened out by Rule 702 and 703. And Rule 403 instructs the district court in permissive rather than mandatory terms. But Rule 403 clearly provides an additional textual basis for excluding scientific testimony based on theories or techniques not generally accepted by the relevant scientific community. In light of the truth-seeking purpose of the rules as a whole, "[a] false aura of scientific infallibility, coupled with low probative value, increases resistance to admitting evidence since it multiplies the hazards of misleading a jury." *In re "Agent Orange" Product Liability Litigation*, 611 F. Supp. at 1256.

Application of the General Acceptance Rule to This Case. The scientific opinion testimony principally at issue in this case was based on reanalyses of epidemiological studies conducted by other researchers. The district court rejected these opinions because the reanalyses had neither been subjected to critical review by other scientists nor otherwise shown to conform to accepted scientific techniques.

For example, the district court rejected the proffered testimony of Dr. Shanna Swan. Dr. Swan had "reanalyzed" a study conducted by the Centers for Disease Control (CDC), but she agreed that she had "never written up the study or paper so that someone can actually look at and consider how you actually arrived at your data." JA 141. Her "reanalysis" lacked generally acceptable indicia of scientific reliability: it was financed by plaintiff's attorneys solely for the purpose of litigation, JA 138, and it was not made available for examination and verification by members of the scientific community.[42] The court properly ruled that under the circumstances her "unsupported" allegation that statistics link Bendectin to birth defects was "insufficient." JA 236.[43]

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[42] Dr. Swan's conclusions appeared in a one-paragraph abstract describing an upcoming conference presentation, but that 200-word summary did not provide details sufficient for scientific evaluation of her reanalysis. JA 141; Shanna Swan, *Methodological Issues in the Study of Prenatal Drug Exposures and Congenital Malformations: Bendectin Reanalyzed* (abstract) 120 AM. J. OF EPIDEMIOL. 486, 486-87 (1984). *See DeLuca v. Merrell Dow Pharmaceuticals*, 791 F. Supp 1042, 1050 (D.N.J. 1992) (Dr. Swan provided no explanation for never submitting her reanalysis for publication).

[43] The same evidence had been proffered in *Lynch v. Merrell-Nat'l Lab.*, 830 F.2d at 1195. That court said that Dr. Swan's reanalysis consisted of selecting a *subset* of the participants in a CDC study and comparing the children of Bendectin users to children born with Down's syndrome. The court rejected this reanalysis because there was no proffered scientific basis to exclude the possibility that a lower

Two other witnesses offered by plaintiffs had also performed "reanalyses" lacking indicia of reliability. Dr. Jay Glasser and Dr. Alan Done would testify to their unpublished calculations that revisited previous studies by selecting from within already small population samples. Like Dr. Swan, knowing the results plaintiffs wanted, they conducted their unique reanalyses, sifting through 63 and 31 participants respectively to select even smaller samples.[44] In *DeLuca v. Merrell Dow Pharmaceuticals*, 791 F. Supp. 1042 (D.N.J. 1992), on remand from the Third Circuit, *DeLuca v. Merrell Dow Pharmaceuticals*, 911 F.2d 941 (3d Cir. 1990), the District Court found Dr. Done's reanalysis testimony so riddled with errors as to be inadmissible. His precise method of calculations "was a mystery and was not in conformance with any known methodology," 791 F. Supp. at 1048; qualified epidemiologists could not replicate his recalculations, *id.*; he had mistakenly transposed entries of data, *id.* at 1049; he had included studies of women who had ingested ingredients not found in Bendectin, *id.*; and he had ignored two contrary studies of women who did ingest Bendectin, *id.* at 1051.

The issue, of course, is not whether "reanalysis" of a statistical study is an accepted technique. It is whether particular reanalyses, performed for the purpose of litigation and involving adjustments to the database so as to change the numerators and denominators of the pertinent fractions, but not written up or submitted for review by other scientists, constitute "scientific . . . knowledge." In this case, the reanalyses contradicted the findings of more

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incidence of limb reduction birth defects was attributable to the same genetic defect that causes Down's syndrome. *Id.*

[44] *Brock*, 874 F.2d at 312; *Lynch*, 830 F.2d at 1195. The Ninth Circuit opinion in this case said the courts in *Brock* and *Lynch* considered "largely the same evidence presented to the district court below." JA 239.

than thirty other studies, JA 238, were prepared solely for purposes of litigation, condoned a wider margin of error than the usual 95 percent confidence interval, JA 151, involved selection from samples so small that slight adjustments could easily affect the result, had not been reviewed by others in the field (indeed were not even accessible to others), and were not otherwise shown to have been carried out in a manner that other scientists would accept. The district court's determination that testimony based on these reanalyses was not testimony as to "scientific . . . knowledge" was entirely correct.

CONCLUSION

The decision of the United States Court of Appeals for the Ninth Circuit should be affirmed.

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WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

On Petition for Writ of Certiorari
to the United States Court of Appeals
for the Ninth Circuit

BRIEF AMICUS CURIAE OF THE AMERICAN COLLEGE OF LEGAL MEDICINE IN SUPPORT OF THE RESPONDENT

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No. 92-102

In The

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October Term, 1992

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Respondent.

On Petition for Writ of Certiorari
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for the Ninth Circuit

BRIEF AMICUS CURIAE OF THE AMERICAN COLLEGE OF LEGAL MEDICINE IN SUPPORT OF THE RESPONDENT

INTEREST OF AMICUS

The American College of Legal Medicine (ACLM) respectfully submits this brief as amicus curiae in support of the respondent. ACLM has received consent of both parties to submit this brief pursuant to the Rules of this Court.

Founded in 1960, the ACLM is the official organization for professionals concerned with issues arising at the convergence of law and medicine. ACLM is a professional community of about 1300 physicians, attorneys, allied health professionals, administrators, scientists, and others with a sustained interest in

medicolegal affairs. The organization is officially recognized by the American Medical Association (AMA) as the society that represents legal medicine specialists and it holds a seat in the AMA House of Delegates.

As an organization whose membership consists of both attorneys and physicians, ACLM plays a significant role in the dialogue of medicolegal affairs. With very few exceptions, those individuals who are Fellows of ACLM, as opposed to other members, are trained and have degrees in both law and medicine, and are able to apply the insights of one profession to the problems of the other. Thus, ACLM is a unique organization confronting issues at the intersection of law and medicine. Furthermore, ACLM is not a partisan organization as its membership consists of plaintiff and defense attorneys, corporate and public interest attorneys and medical professionals in almost every specialty. Many members of ACLM confront scientific evidence in the courtroom on a regular basis as advocates or as expert witnesses. Therefore, ACLM can provide guidance, both seasoned and objective, that will be available nowhere else.

ACLM is concerned that invalid and unreliable scientific testimony is confounding our legal system and its search for truth. The Federal Rules of Evidence and current judicial practice do not provide an effective check on the credibility of the foundation of an expert's testimony. This organization considers the objective evaluation of the basis of an expert's scientific testimony, prior to any determination of its admissibility, an issue of paramount importance to all parties and their attorneys in litigation. Therefore, ACLM believes that the judiciary should establish criteria for evaluating the foundation of an expert's testimony. It is entirely consistent with the allocation of responsibility under the Federal Rules of Evidence for the judiciary to require that a specific threshold of reliability be satisfied before permitting the expert's testimony.

STATEMENT OF THE CASE

Amicus adopts the statement in Respondent's Brief In Opposition To Petition, pp. 4-9.

SUMMARY OF ARGUMENT

The purpose of codifying the Federal Rules of Evidence in 1975 was to achieve consistency. Jay A. Gold, *Limiting Judicial Discretion to Exclude Prejudicial Evidence*, 18 U.C. Davis L. Rev. 59, 83 (1984). While the Federal Rules of Evidence require a threshold scrutiny of expert testimony by trial judges, the Rules have not provided sufficient guidance to achieve their purpose. Inconsistencies among the federal courts regarding expert testimony stem from unresolved questions concerning application of the Rules.[1]

ACLM urges the courts to assume greater responsibility in defining an evidentiary threshold in order to ensure comparable treatment in evaluating the foundation of an expert's scientific testimony, no matter which court is applying the Federal Rules of Evidence. In so doing, ACLM urges this Court to adopt the criteria used by scientists themselves in determining scientific credibility. That is, courts should consider whether an expert's testimony relies upon a study which has undergone controlled experimentation, produced statistically significant results, and was published and peer reviewed by the relevant scientific community. ACLM urges this Court to adopt the criteria discussed herein, as an evidentiary threshold, or floor, of reliability to determine the trustworthiness of the foundation of an expert's testimony. By adopting the criteria suggested herein, this Court will enable trial courts and juries to make more informed and accurate decisions based upon a clearer understanding of the scientific strengths and weaknesses of the foundation of an expert's testimony. As a consequence, the interest of justice will be far better served.

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[1] *See Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 310-11 (5th Cir. 1989) (advocating careful judicial inspection of expert testimony), *cert. denied*, 494 U.S. 1046 (1990); *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1534-35 (D.C. Cir. 1984) (allowing the jury to assess the weight of expert testimony), *cert. denied*, 469 U.S. 1062 (1984).

ARGUMENT

> What is important in a scientific . . . theory is above all that it should be true or at least seriously or solidly grounded.
>
> Pope John Paul II[2]

I. ACCEPTANCE BY THE SCIENTIFIC COMMUNITY IS AN ESSENTIAL GUIDE TO THE TRUTH OF SCIENTIFIC STATEMENTS

On October 31, 1992, a papal commission issued a report on Galileo, condemned in the seventeenth-century by the Roman Catholic Church for advocating the Copernican hypothesis. The report admitted that none of Galileo's adversaries, at his time or since, has "discovered anything that could constitute a convincing refutation of Copernican astronomy."[3] Pope John Paul II agreed that the case of Galileo has "long been shelved and . . . the errors committed [have] been recognized."[4]

Galileo's condemnation has become the paradigm of the failure to accept scientific evidence which turned out to be true. Those whose scientific conclusions do not conform to the conventional standards of the scientific community are quick to invoke Galileo's name, and to claim that they, too, will enjoy future vindication. Invocations of the Galileo case are, though, inappropriate. Acceptance of his hypotheses eventually occurred due to their conformance with the criteria set forth herein. Triers of fact, however, cannot be guided by theories that *may* be shown to be true years into the future depending on the outcome of scientific investigation. The importance of scrutiny by the scientific community as a guide to the truth of scientific statements could not be better exemplified than by the recent observations about the Copernican theory.

The scientific enterprise is predicated on the idea that careful observation and calculation of specially-collected data will yield

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[2] Pope John Paul II, *Lessons of the Galileo Case,* 22 Origins 309, 373, Vol. 22, No. 22 (November 12, 1992).

[3] Cardinal Paul Poupard, *Galileo: Report on Papal Commission Findings,* 22 Origins 374, 375, Vol. 22, No. 22 (November 12, 1992).

[4] Pope John Paul II, *Lessons of the Galileo Case,* 22 Origins 369, 371, Vol. 22, No. 22 (November 12, 1992).

truths that cannot be arrived at by ordinary, everyday reasoning about common experience. Every scientific discovery since the Scientific Revolution, from Galileo's own discovery that heavy bodies fall at the same rate as lighter ones, testifies to the validity of this idea.

Testimony in the courtroom, like science, should be directed to discovering truth – in this instance, truth about matters in controversy in a particular case. Where scientific questions are at issue, evidence traditionally has been presented by expert testimony. As the truths of science frequently contradict the superficial conclusions of common sense, it is often necessary for experts to interpret scientific results in their field for the court and jury.

The principal argument for reviewing the foundation of an expert's testimony prior to its introduction to the jury is concern over the ability of lay jurors to appropriately evaluate the validity and reliability of the basis of an expert's scientific testimony. Jurors cannot fully appreciate the limitations of expert testimony, so the court must initially review the credibility of the foundation of such testimony. As Judge Learned Hand observed, expert testimony creates the risk of a special kind of prejudice:

> The trouble . . . is that it is setting the jury to decide, where doctors disagree. The whole object of the expert is to tell the jury, not facts . . . but general truths derived from specialized experience. But how can the jury judge between two statements each founded upon an experience confessedly foreign in kind to their own? It is just because they are incompetent for such a task that the expert is necessary at all.

Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony,* 15 Harv. L. Rev. 40, 53 (1901). Hence, it is of the utmost importance that the testimony submitted for the trier of fact's consideration be scientifically credible from the start.

In the minds of many, if not most, courts, the problem is compounded because lay jurors are in awe of scientific testimony and tend to overestimate its probative value. *See United States v. Baller,* 519 F.2d 463, 466 (4th Cir. 1975) ("because of its apparent objectivity, an opinion that claims a scientific basis is apt to

carry undue weight with the trier of fact") *cert. denied,* 423 U.S. 1019 (1975); *United States v. Addison,* 498 F.2d 741, 744 (D.C. Cir. 1974) (scientific evidence may assume a posture of mystic infallibility in the eyes of a jury of laymen); *United States v. Amaral,* 488 F.2d 1148, 1152 (9th Cir. 1973) ("scientific or expert testimony particularly courts the . . . danger [of undue prejudice or of confusing the issues or misleading the jury] because of its aura of special reliability and trustworthiness"); *D'Arc v. D'Arc,* 385 A.2d 278 (N.J. Super. Ct. Ch. Div. 1978) (in refusing to admit voiceprint evidence, the court emphasized that this evidence could assume an "aura of mystic infallibility in the eyes of a jury of laymen.") *aff'd,* 421 A.2d 602 (N.J. Super. Ct. App. Div. 1980). Even objective jurors, without sympathy or malice for either party, may resolve issues of fact on the basis of an expert's impressive demeanor or credentials rather than upon the substance of his or her testimony. In order to insure that the outcome of a trial hinging upon scientific testimony does not conflict with the opinions recognized by the scientific community, objective criteria for evaluating the basis of an expert's testimony are needed.

II. THE COURT SHOULD DEVELOP AN EVIDENTIARY THRESHOLD FOR THE ADMISSIBILITY OF SCIENTIFIC TESTIMONY

A. The Federal Rules of Evidence Support Judicially-Created Doctrines.

The goal of our legal system is just resolution of disputes. In achieving that goal, it is necessary to discover the truth, the whole truth, and nothing but the truth, and the Federal Rules of Evidence have been fashioned with that in mind. Thus, the Rules require a threshold scrutiny of an expert's testimony by trial judges under Fed. R. Evid. 104(a), 401, 702, 703 and 403 to determine its relevance, usefulness and credibility. *See Salem v. United States Lines Co.,* 370 U.S. 31 (1962); *In Re Air Crash Disaster at New Orleans,* 795 F.2d 1230, 1233-34, (5th Cir. 1986); *Gideon v. Johns-Manville Sales Corp.,* 761 F.2d 1129, 1135 (5th Cir. 1985); *United States v. Trice,* 476 F.2d 89 (9th Cir. 1973), *cert. denied,* 414 U.S. 843 (1973). The Rules, however, do not provide sufficient guidance to judges faced with the task of assessing technical, scientific, expert testimony. A court should

not allow the introduction of scientific, expert testimony unless it finds, as a preliminary matter, that the bases of the expert's opinion are valid and reliable. *See Slaughter v. Southern Talc Co.,* 919 F.2d 304, 307 (5th Cir. 1990).

The drafters of the Rules appreciated the need for flexibility on the part of the trial-court judges in exercising their "gatekeeper" responsibility. *See* Advisory Committee's Notes, accompanying Fed. R. Evid. 104(a). Accordingly, the Rules permit judicially-created doctrines, such as the one created in *Frye v. United States,* 293 F. 1013 (D.C. Cir. 1923), to help lead trial courts through the maze of credentials, opinions, methodology, research designs, and unbridled self-interest that inevitably confuse the trier of fact in weighing expert testimony. *See also United States v. Pryba,* 678 F. Supp. 1225, 1232-35 (E.D. Va. 1988); *Stites v. Sundstrand Heat Transfer Inc.,* 660 F. Supp. 1516, 1523 (W.D. Mich. 1987).

Although *Frye* and the Federal Rules of Evidence attempt to set forth standards for the admissibility of expert testimony, both are insufficient to guide judges faced with the task of assessing the validity and reliability of the basis of an expert's technical, scientific testimony. The consensus-standard mandated by *Frye* leaves too many questions unanswered. For example: (1) what percentage of those in the field must accept the technique;[5] and (2) whether general acceptance refers to the technique, the underlying principles or both. The adoption of the Federal Rules of Evidence did not resolve the questions raised by *Frye.* Quite the contrary, the Rules further confuse the issue. First, the Rules are silent on whether the general-acceptance test has been superceded. Second, the "reasonably-relied-upon-by-experts" standard offers no more clarity or guidance to the courts than *Frye.*

ACLM urges this court to focus the standard on the *reliability* of the basis of an expert's testimony. In order for judges to assess the reliability of the foundation of an expert's scientific testimony,

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[5] One court defined "general acceptance" as "widespread; prevalent; extensive though not universal." *United States v. Zeiger,* 350 F. Supp. 685, 688 (D.D.C. 1972), *rev'd,* 475 F.2d 1280 (D.C. Cir. 1972) while another defined it as a "substantial section of the scientific community." *United States v. Williams,* 443 F. Supp. 269, 273 (S.D.N.Y. 1977) *aff'd,* 583 F.2d 1194 (2d Cir. 1978), *cert. denied,* 439 U.S. 1117 (1979).

courts need objective criteria to guide their decision-making. The criteria should permit only those techniques that provide accurate results and those methods or modes of reasoning that provide reliable conclusions. ACLM asserts that establishing objective criteria for evaluating the reliability of the foundation of an expert's testimony is necessary and is consistent with the Federal Rules of Evidence.

B. The Criteria Guiding The Courts In Evaluating The Foundation Of An Expert's Scientific Testimony Should Be The Same As Are Applied By The Scientific Community

The desideratum in promulgating criteria for evaluating the foundation upon which scientific testimony is based is quite clear: what will be most likely to include expert testimony that is based upon scientific tests and techniques whose results are *valid*, and to exclude testimony whose bases are *invalid*? More broadly, what criteria will make it most likely that the testimony will assist the trier of fact to reach a conclusion that is, indeed, the correct conclusion?

In developing criteria for scientific proof, there are two dangers that must be avoided. One danger is that testimony may be excluded inside the courtroom that is clearly accepted outside the courtroom in scientific circles. This danger has frequently materialized – judges have come under severe criticism for their excessive caution about allowing juries to hear and to evaluate testimony that is based upon scientific test procedures, and to give such test results less probative weight than they warrant.[6] The most notorious – but far from the only – instance of injustice in this regard was the 1946 case of *Berry v. Chaplin*, 169 P.2d 442 (Cal. Dist. Ct. App. 1946), in which the actor Charlie Chaplin was forced to pay child support for a child which blood testing had conclusively shown could not have been his.[7]

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[6] *See e.g.*, W. Curran, *Law-Medicine Notes*, xvii (1989).

[7] The blood test was admitted into evidence but the jury was permitted to consider the mother's "equally persuasive" testimony that Chaplin was the father. *See* Gold, *Science Tests Now Get Their Day In Court*, N.Y. Times, January 23, 1992, p. A12, col. 3; *See also, State v. Aquilera*, 25 Cnml. Rep. (BNA) 2189 (Dade Cty. Fla. 1979) radar case; *State v. Vail*, 274 N.W.2d 127 (Minn. 1979) drug testing case.

The second danger, which also has come to pass far too often, is that triers of fact have been allowed to consider procedures and opinions that have little or no credibility in scientific circles, and that, in many instances, are unsupported by any semblance of scientific verification.[8] *See Sterling v. Velsicol Chemical Corp.*, 855 F.2d 1188 (6th Cir. 1988) (the district court awarded damages to all plaintiffs for immune system impairment based upon the testimony of a clinical ecologist. The Sixth Circuit reversed the awards since the expert's testimony was based upon clinical ecological tests which had been rejected by professional societies as unproven methodology lacking any scientific basis in fact or theory); *United States v. Tranowski*, 659 F.2d 750 (7th Cir. 1981) (the district court permitted testimony by an astronomer who claimed he could analyze the dates on which photographs in evidence were taken. The Seventh Circuit reversed since the expert's chart was unverified for its accuracy in dating photographs).

The goal must be to avoid both of these divergent dangers, and to maximize the likelihood that the conclusions reached by the trier of fact will be based upon the truth. The criteria guiding the courts in evaluating the foundation of an expert's scientific testimony, therefore, should be the same criteria as those applied by members of the scientific community who are learned in the relevant area, and, who more than anyone else, can be expected

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[8] P. Huber, *Galileo's Revenge: Junk Science In The Courtroom* (1991) details many shocking instances of expert testimony with little or no scientific verification: *e.g. Norris v. Gatts*, 738 P.2d 344 (Alaska 1987) (without studies to support the basis of his opinion, the expert testified that the throttle in defendant's car had jammed at exactly the same instant the car's brakes temporarily failed); *Elam v. Alcolac, Inc.*, 765 S.W.2d 42 (Mo. Ct. App. 1988) (contrary to the opinion of the relevant scientific community, expert testimony by a clinical ecologist was that the pollution produced by the defendant-manufacturer, damaged the immune systems of families living in the area); *Menarde v. Philadelphia Transportation Co.*, 103 A.2d 681 (Pa. 1954) (family physician testified without proof that the accident in which plaintiff was bruised while alighting from a streetcar was the direct cause of her breast cancer); *National Dairy Products Corp. v. Durham*, 154 S.E.2d 752 (Ga. 1967) (physician testified without supporting verification that "trauma induced by pressure from a seat belt might have led to an inflammatory condition of plaintiff's testicles," which might "conceivably" have triggered cancer in his left testicle). *See also*, N. Angier, *Supreme Court Is Set to Determine What Science Juries Should Hear*, N.Y. Times, January 2, 1993, p. 1, col. 1.

to understand the reliability of scientific tests and the validity of their results.

C. The Criteria Applied By The Scientific Community Include Controlled Study, Statistical Significance, Publication And Peer Review

In considering whether the foundation of an expert's opinion is credible, scientists are concerned whether the opinion is properly supported. They invariably ask: (1) Whether a controlled study has been performed?; (2) Were the results of the study statistically significant?; and (3) Was the study published in a peer-reviewed journal?

1. Has a "controlled" study been performed? Any study that purports to reach a conclusion as to how a substance or technique affects human beings must be controlled. That is, the outcome must be compared to some standard in order to determine what effect, if any, may be attributed to the technique or substance under study. Without a basis of comparison, no serious conclusions may be drawn from the study.[9] A leading textbook of epidemiology states:

> [T]he reader [of scientific studies] should always ask, *Compared to what*? This initial question will usually imply others, such as, *Was there a control or comparison group? Who constituted the control group? Were they similar to the treated group in all important respects other than the treatment*? The author [of the study] should have provided clear and satisfying answers to these questions in the paper. If not, there is good reason to doubt the claimed [results].

G. Friedman, *Primer of Epidemiology*, 241 (3d ed. 1987) (emphasis in original).

Controls are important because, in every branch of science, precautions must be taken so that conclusions are not drawn on the basis of factors that are irrelevant to the study. For example, people with Alzheimer's disease are much more likely

[9] "The effectiveness of a treatment can only be meaningfully assessed by evaluating its performance relative to some alternative or control treatment." T. Hassard, *Understanding Biostatistics*, 188 (1991).

to die than those without it, but that is not because Alzheimer's itself is fatal. Rather, it is because individuals with Alzheimer's tend to be much older than the average person. In the evaluation of medications and therapeutic measures, the principal precaution taken is the use of a control group. In a controlled study, a group of experimental subjects is given a certain regimen, and the outcome for that group is compared with the outcome for another nearly identical group, called the control group, that is not given the regimen. So in the Alzheimer's example, members of the control group would be the same age as members of the Alzheimer's group. What is essential is that the expert opinion be based on a comparison between those exposed and those not exposed to the substance or technique in question. Where a study is not controlled, there is no way of knowing to what to attribute the observations that result, and, hence, the scientific community will not seriously consider the findings of the study.

2. If the testimony is based upon a statistical study, were the results of the study statistically significant? Even if a controlled study shows a difference in outcome between the two groups, that difference might be due to chance alone. Thus, statistical analysis is performed to ascertain the odds that the outcome was likely to have been due to chance. A leading textbook of medical statistics states: "Among the statistical methods employed in medical research, tests of significance enjoy a preeminent position." D. Matthews and V. Farewell, *Using and Understanding Medical Statistics*, 11 (2d ed. 1988). It further notes that "a test of significance is a statistical procedure by which one determines the degree to which collected data are consistent with a specific hypothesis which is under investigation." *Id.*

Obviously, where testimony is based upon conclusions drawn from collected data, it is important to know how likely it is that those conclusions may legitimately be drawn from those data. In general, a certain odds level (usually 95%, or 19-to-one) is considered the threshold of statistical significance, and the results of a study are considered significant[10] only if the odds that the effect was due to the substance or technique in question are greater than the stated threshold. Statistically insignificant results may

[10] J. Last, *Maxcy - Rosenau Public Health and Preventive Medicine*, 50 (12th ed. 1986).

be interesting and considered suggestive by some, but they are universally considered inconclusive in the scientific community. While no particular threshold of statistical significance is implied by the Federal Rules of Evidence, a test of significance should be reported for all statistical studies upon which an expert relies as the basis of his or her testimony. Such tests of statistical significance should be made available to judges when they are determining the validity and reliability of the basis of an expert's testimony. If the results of a study are very likely due to chance, then such a study should not be considered valid and should not be admissible.

3. Was the study published in a peer-reviewed journal? Science does not generate exact knowledge with logical certainty. Instead, it relies on the give and take of criticism, testing, experimentation, and review to determine if it is valid. *See* Bert Black, A *Unified Theory Of Scientific Evidence*, 56 Fordham L. Rev. 595 (1988). Acceptance is the fundamental test scientists use to decide validity of theories and reasoning in any given context. Because acceptance is predicated on a process of refinement and critical review, communication among scientists is a necessity; hence, the importance of publication and peer review cannot be disregarded. Publication and peer review serve as an evidentiary threshold of validity in science. If a theory is not accepted anywhere in the scientific literature, strong doubts about its validity inevitably arise among the scientific community.

The peer review process is based upon established procedure in the scientific community. Once a scientific experiment is completed, the results are submitted to a scientific journal in the field. The journal sends the results, without information identifying the author, to several "referees", i.e., scientists recognized for their work in the relevant field. There are several factors that referees look for in deciding whether or not to approve a paper for publication. Most important, they attempt to assure that the paper meets scientific standards. There are two questions that referees ask in order to carry out this latter function. First, they ask whether the paper is consistent with the scientific method in the particular field. They will examine the methodology employed, the data obtained, the analyses performed, and the conclusions drawn by the authors. Second, they ask whether

the paper is internally consistent — whether the data presented in each part of the paper (including tables and graphs) supports the conclusions drawn, or whether the paper contradicts itself in any fashion. On this basis, the referees decide whether or not another draft is needed, and the results will be published only with the approval of the referees.[11]

It is only through this peer review process that courts can determine if an expert's opinion has a valid and reliable *basis*. However, publication and peer review is no guarantee of the validity of the *conclusions* of an experiment. In fact, papers having undergone peer-review have reached conclusions that have drawn justifiable criticism or have been disproved by later research. Nonetheless, no reputable scientist would credit a scientific result that had not gone through this peer review process. Publication in a peer-reviewed journal is thus a necessary element for scientific credibility.

A growing number of courts require that scientific evidence upon which an expert's testimony is based undergo peer review before it is allowed into evidence.[12] These courts' insistence upon publication and peer review reflects an acknowledgment of their inability to distinguish the disputes over methodology and design errors in scientific studies. Furthermore, these courts have adopted the publication and peer review requirements as

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[11] *See* S. Lock, *A Difficult Balance: Editorial Peer Review in Medicine* (3d. ed. 1991).

[12] *See Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989) (rejected an expert's testimony in part because the expert had neither published his recalculations nor offered them for peer review); *Lynch v. Merrell-National Laboratories Division of Richardson-Merrell, Inc.*, 830 F.2d 1190 (1st Cir. 1987) (rejected reanalysis of epidemiological data because it had never been published in a scientific journal or elsewhere, and, therefore, could not form the foundation for an expert opinion challenging scientific consensus); *Perry v. United States*, 755 F.2d 888 (11th Cir. 1985) (affirmed exclusion of an epidemiological study on swine flu because it had not been peer reviewed); *Ellis v. International Playtex, Inc.*, 745 F.2d 292 (4th Cir. 1984) (publication and survival of peer review is one further indication that the reliability of the contested data far exceeds that normally accorded preliminary data and speculation); *Johnston v. United States*, 597 F. Supp. 374 (D.C. Kan. 1984) (this court was disappointed with the apparent fact that the "so-called experts can take such license from the witness stand; these witnesses say and conclude things that in the Court's view, they would not dare report in a peer-reviewed journal").

surrogate screening devices. *See* Michael Green, *Expert Witnesses And Sufficiency Of Evidence In Toxic Substances Litigation: The Legacy Of Agent Orange And Bendectin Litigation*, 86 NW. U. L. Rev. 643 (1992). The insistence by these courts of the publication and peer review criteria also reflects a recognition that a jury on its own might well have difficulty in accurately assessing the strengths and weaknesses of such scientific data and methodology.

The real question is whether the courts, or juries themselves, can develop an equally refined screening mechanism as publication and peer review for determining the credibility of scientific studies. ACLM asserts that the answer to that question is a resounding "no." Without an evidentiary threshold of validity for evaluating the foundation of an expert's testimony, the enormously difficult task of distinguishing credible from incredible science will continually burden judges and juries and result in unfair awards based upon unreliable testimony.

D. The Determination Of The Validity And Reliability Of The Foundation Of An Expert's Testimony Cannot Be Made Solely By Application Of The Federal Rules Of Evidence.

When scientific testimony is proffered, the judge has an obligation to screen the testimony prior to trial.[13] *United States v. Eskow*, 422 F.2d 1060 (2d Cir. 1970), *cert. denied*, 398 U.S. 959 (1970). In the courts' search for truth, expert testimony should not be admitted unless there are objective indicia that the testimony is valid and reliable. In essence, the court is the filter by which the purity of scientific truths can be evaluated and then allowed to be judged by the trier of fact. In making its determination as to this preliminary question of fact under Federal Rules of Evidence Rule 104(a), a court is not bound by the rules of evidence, except the rules of privilege. *United States v. Haldeman*, 559 F.2d 31 (D.C. Cir. 1976), *cert. denied*, 431 U.S. 933 (1977). While Rule 104(a) recognizes the court's ability to receive all relevant evidence and to discount evidence that is

[13] Rule 104(a) entrusts all preliminary questions concerning the admissibility of evidence to the trial court, and expressly frees trial-court judges from the rules of evidence in making that determination.

untrustworthy or suspicious, it permits "filtering" without uniform standards. *Seiler v. Lucasfilm, Ltd.*, 797 F.2d 1504 (9th Cir. 1986), *modified*, 808 F.2d 1316 (9th Cir. 1986), *cert. denied*, 484 U.S. 826 (1987). The resulting problems have been discussed above. By applying the balanced criteria recognized by the scientific community set forth herein, the courts will have a more consistent road map when making a determination as to the trustworthiness of the basis of an expert's scientific testimony.

In screening expert testimony, judges are guided by Federal Rules of Evidence 401, 702, 703 and 403. These Rules, too, however, provide only a framework and insufficient guidance for judges faced with the task of determining whether the foundation of an expert's testimony is reliable and, therefore, relevant, useful to the jury and credible.

Rule 401 defines *relevant* evidence as "having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." In drafting the Rules, the Advisory Committee rejected the formulation of relevancy found in the Uniform Rules of Evidence (1953) because it overemphasized the "logical process" to the detriment of the "experience of science." *See* Advisory Committee's Notes accompanying FRE 401.

Relevancy encompasses questions about both the validity of the scientist's reasoning and the reliability of his conclusions. *See* Bert Black, *A Unified Theory of Scientific Evidence*, 56 Fordham L. Rev. 595 (1988). Black explains the distinction between validity and reliability as follows:

> Validity and reliability, though intertwined, are very different concepts. One normally speaks of "valid" rather than "reliable" reasons or theories, and of "reliable" rather than "valid" instruments or machines. Reliability means that a successful outcome, or a correct answer, is sufficiently probable for a given situation. In contrast to reliability, validity means that which results from sound and cogent reasoning. An invalid conclusion cannot be reliable, yet valid reasoning does not necessarily lead to reliable conclusions. Reliability is the ultimate legal concern,

> but when it hinges on controversial, contested reasoning, the validity of the reasoning must be addressed. *Id.* at 599.

Whether scientific testimony is valid depends upon accepted scientific practice and the soundness of the reasoning leading to the expert's conclusion. Analyzing the validity of an expert's methodology or reasoning involves determining whether the facts are connected to the expert's conclusion in a scientifically valid way. This, in turn, is decided by determining whether a reasonable scientist in the field would find the methodology, or mode of reasoning, used by the expert relevant to the conclusions drawn by the expert. *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1111 (5th Cir. 1991) (per curiam), *cert. denied*, 112 S. Ct. 1280 (1992).

It is apparent, then, that judges cannot simply rely on "logic" and "experience" alone to evaluate the relevance of scientific testimony but, rather, must turn to science for assistance and solicit information bearing on the validity and reliability of the foundation of the testimony. Accordingly, the courts' threshold for determining reliability should be no less than and no greater than that recognized by the scientific community.

Rule 702 states that expert testimony is admissible "if scientific, technical or other specialized knowledge will *assist the trier of fact*" in understanding the issues and the witness is qualified as an expert. The "assist-the-trier-of-fact" test subsumes a relevancy analysis which, in turn, assumes a threshold of reliability. *United States v. Jakobetz*, 955 F.2d 786, 796 (2d Cir. 1992) *citing*, 3 Weinstein & Berger, *Weinstein's Evidence*, 702[02] at 18. Rule 702, therefore, supports the proposition that expert testimony based upon a technique or methodology which is not scientifically credible, is unhelpful, and, therefore, excludable. *See Slaughter v. Southern Talc Co.*, 919 F.2d 304, 307 (5th Cir. 1990); *United States v. Downing*, 753 F.2d 1224 (3d Cir. 1985). Nowhere does the language of the Federal Rules of Evidence guide the courts in their task of determining scientific credibility. The criteria set forth herein would fill this void and enable the courts

to carry out their function in a more consistent manner under the Federal Rules of Evidence.[14]

Moreover, Federal Rule 703 requires the court to examine, as a threshold matter, the reasonableness of the expert's reliance on his or her data or methodology.[15] This examination necessarily entails consideration of the validity and reliability of the data or methodology. Rule 703 highlights the need for information regarding the trustworthiness, *i.e.*, the validity and reliability of the sources relied upon by an expert in forming his opinion, by noting:

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[14] The Committee on Rules of Practice and Procedure of the Judicial Conference of the United States has recognized the need to revise Rule 702. Its proposed changes to the language of Rule 702 state:

> Testimony providing scientific, technical, or other specialized information, in the form of an opinion or otherwise, may be permitted only if (1) the information is *reasonably reliable* and will *substantially assist* the trier of fact to understand the evidence or to determine a fact in issue and (2) the witness is qualified as an expert by knowledge, skill, experience, training, or education to provide such testimony . . . (emphasis added)

These changes, however, do nothing to clarify the evidentiary threshold. They still do not provide the courts with the guidance needed in determining whether the bases of the expert's opinions are scientifically credible, and, therefore, relevant, useful to the trier of fact and more probative than prejudicial. *See Fix the Law of Experts*, Litigation, Fall 1992, Vol. 19, No. 1 at 21-22.

[15] Although the proposed Federal Rules of Evidence reflect a general trend toward more liberal admission of evidence, the commentary to Proposed Rule 703, regarding Bases of Opinion Testimony by Experts, suggests that the drafters intended to preserve judicial power to exclude particular categories of "expert testimony":

> If it be feared that enlargement of permissible data may tend to break down the rules of exclusion unduly, notice should be taken that the rule requires that the facts or data "be of a type reasonably relied upon by experts of a particular field." The language would not warrant admitting in evidence the opinion of an "accidentologist" as to the point of impact in an automobile collision based on statements of bystanders, since this requirement is not satisfied.

The House of Representatives' version of the Federal Rules of Evidence, approved on February 6, 1974, retains Rule 703 in the same form as promulgated by the Supreme Court. See H.R. 5463, 93d Cong. 1st Sess. (1974). *United States v. Addison*, 498 F.2d 741, 743 n.5 (D.C. Cir. 1974).

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to him at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

The second sentence of Rule 703 aims to bring expert witness practice in the courtroom in line with that of experts in their respective professions. *See* Advisory Committee's Notes accompanying Fed. R. Evid. 703. Rule 703 allows an expert to rely on any basis, otherwise admissible into evidence or not, as long as other experts in the field would "reasonably" rely upon that basis. *See Viterbo v. Dow Chemical Co.*, 826 F.2d 420 (5th Cir. 1987); *Renaud v. Martin Marietta Corp.*, 749 F. Supp. 1545 (D.C. Colo. 1990), *aff'd*, 972 F.2d 304 (10th Cir. 1992); In Re *"Agent Orange" Product Liability Litigation*, 611 F. Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied, sub. nom, Lomardi v. Dow Chemical Co.*, 487 U.S. 1234 (1988); *Zenith Radio Corp. v. Matsushita Electric Industrial Co., Ltd.*, 505 F. Supp. 1313 (E.D. Pa. 1980).

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 727 F. Supp. 570 (S.D. Cal. 1989), *aff'd*, 951 F.2d 1128 (9th Cir. 1991), *cert. granted*, 113 S.Ct. 320 (1992), the defendant presented evidence that of 30 published studies involving over 130,000 patients, not one published epidemiologic study had demonstrated a statistically significant association between Bendectin and birth defects. Plaintiffs' evidence of causation consisted primarily of expert opinion based upon in vitro and in vivo animal tests, chemical structure analyses and the reanalysis of epidemiologic studies. The district court correctly determined that plaintiffs could not meet their burden of proving Bendectin caused birth defects and granted defendant's motion for summary judgment. *Id.*, at 576. The study upon which the plaintiffs relied was simply a recalculation of the data from a previously published epidemiologic study. The "recalculation study," however, was never published nor subject to peer review, and it did not meet the level of confidence to be deemed statistically significant. Therefore, the court ruled the evidence insufficient to take this

matter to a jury. *Id.* The Ninth Circuit affirmed, reiterating that the courts are unwilling to allow plaintiffs to rely on the reanalysis of epidemiologic studies because the reanalysis had neither been published nor subjected to the rigors of peer review especially in light of the massive weight of the original published studies supporting the defendant's position, all of which had undergone full scrutiny from the scientific community. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128, 1131 (9th Cir. 1991). Thus, the recalculation study by plaintiff's expert was not "of a type reasonably relied upon by experts in the particular field."

Finally, Federal Rule of Evidence 403 provides that expert opinions must have a foundation sufficient to make the evidence more probative than prejudicial. If an opinion is fundamentally unsupported by valid and reliable methodology, then it offers no expert assistance to the trier of fact, and that lack of reliable support renders an opinion substantially more prejudicial than probative. *Viterbo v. Dow Chemical Co.*, 826 F.2d 420 (5th Cir. 1987).

Rule 403 requires courts to balance the probative value of otherwise admissible scientific testimony against its potential to mislead the jury. *United States v. Krulewitch*, 145 F.2d 76, 80 (2d Cir. 1944). Determining the extent to which a jury may be misled by invalid expert testimony requires an understanding of the limitations of that testimony. This, in turn, requires knowledge of the methodology or research design, and renders the court dependent upon the expert's assertions. Hence, the bases of an expert's testimony must be credible from the start. Overstatements by experts about the validity and reliability of their methods and conclusions are common. For example, neutron activation analysis has been characterized as being as infallible as fingerprints. *State v. Spencer*, 216 N.W.2d 131, 133-134 (Minn. 1974). Similarly, other overstated assertions have been made for bitemark[16], voiceprint evidence [17], DNA profiling[18], and psychological stress evaluators (PSE)[19]. Application of the criteria set

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[16] *State v. Garrison*, 585 P.2d 563, 566 (Ariz. 1978).

[17] *People v. Kelly*, 549 P. 2d 1240 (Cal. 1976).

[18] *United States of America v. Two Bulls*, 918 F.2d 56 (8th Cir. 1990).

[19] *Smith v. State*, 355 A.2d 527, 535 (Md. Ct. Spec. App. 1976)

forth herein would assist the courts in determining whether the evidence is reliable or if it would mislead the jury.

CONCLUSION

The federal courts have inconsistently applied the Federal Rules of Evidence with respect to the foundation of scientific, expert testimony. ACLM suggests that the solution to this problem is to work within the framework of the Rules, which allow for judicial discretion, and to set forth specific criteria to assist judges in determining whether the foundation of an expert's testimony is reliable and, therefore, whether the testimony is relevant, useful to the trier of fact and more probative than prejudicial.

In the interest of allowing the trier of fact to consider expert scientific testimony that leads to the discovery of truths, ACLM does not suggest that the threshold of validity and reliability be impossibly high. Rather, it should be understood as asking the court to adopt the criteria employed by scientists in the field to determine if the proffered scientific testimony and its underpinnings are reliable and valid. A controlled study, statistical significance, publication and peer review are objective indicia upon which reasonable scientists credit the work relied upon by an expert.

The epidemiological testimony that was proffered in *Daubert* clearly did not meet these criteria, and the Ninth Circuit's decision should be affirmed. The testimony was not credited by reasonable epidemiologists and, therefore, was not valid and reliable and was properly excluded. The focus here is upon the soundness and cogency of the bases of the opinions of those seeking to render scientific testimony. By adopting the balanced criteria suggested herein, the courts will gain a clearer understanding

of the strengths and weaknesses of the foundation of an expert's scientific testimony, and, therefore, fulfill the full intent of the Federal Rules of Evidence.

Respectfully submitted,

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December 11, 1992

VIA FEDERAL EXPRESS

Kenneth J. Chesebro, Esq.
1600 Massachusetts Avenue
Cambridge, MA 02138

RE: Daubert v. Merrell Dow Pharmaceuticals Inc.

Dear Mr. Chesebro:

In our phone conversation today, I informed you that our client, the American College of Legal Medicine, wishes to file an amicus brief with the United States Supreme Court in the above-captioned action.

Pursuant to the Supreme Court rules, we request your consent in that regard. Please sign this letter below and return it to my attention.

Very truly yours,

Elaine Rappaport Lev

ERL:haf

HSF/ERL12-11-1

I, Kenneth J. Chesebro, counsel of record for the Petitioners in the above-captioned matter hereby consent to the filing of an amicus brief by the American College of Legal Medicine in this case.

Kenneth J. Chesebro

APPENDIX A-1

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December 8, 1992

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RE: Daubert v. Merrell Dow, No. 92-102

Dear Ms. Lev:

On behalf of Respondent, I hereby consent to the filing of an amicus brief by the American College of Legal Medicine in this case.

Sincerely,

Richard G. Taranto

Richard G. Taranto
One of Respondent's Counsel

RGT:tj

APPENDIX A-2

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(23)

FILED

JAN 19 1993

OFFICE OF THE CLERK

No. 92-102

In The Supreme Court of the United States

OCTOBER TERM, 1992

WILLIAM DAUBERT AND JASON DAUBERT, Individually And As Guardians Ad Litem For JASON DAUBERT, And ANNA DE YOUNG, Individually And As Guardian Ad Litem For ERIC SCHULLER,

Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

On Writ of Certiorari To The United States Court of Appeals For the Ninth Circuit

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BRIEF AMICUS CURIAE OF AMERICAN INSURANCE ASSOCIATION IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICUS CURIAE*

Amicus curiae, the American Insurance Association ("AIA"), is a national trade organization representing over 250 companies writing property and casualty insurance contracts in every state and jurisdiction of the United States. These companies together wrote policies involving nearly $60 billion in premiums in 1991. AIA member companies are affiliated with thousands of independent insurance agents nationwide. A substantial portion of AIA member companies' business is commercial liability insurance. This form of insurance coverage facilitates the ability of American businesses to provide the goods, services, jobs and investments vital to the country's economic health. In addition, AIA member companies employ more than 145,000 people and contribute $2.2 billion in state taxes and fees (including payroll taxes) to state governments each year.

AIA's purposes include promoting the economic, legislative and public interests of its members and of the insurance industry as a whole; providing a forum for discussion of problems which are of common concern to its members; and serving the public interest through appropriate activities including the promotion of safety and security of persons and property.

AIA members have issued, and continue to issue, insurance policies based upon estimates of risk that take into account the state of scientific knowledge. Whether the Federal Rules of Evidence authorize the courts to exclude expert testimony that is not based upon accepted scientific knowledge is, correspondingly, of great significance to the insurance industry. The free admission of such testimony not only would increase losses under existing policies, but would also result in greater uncertainty in the underwriting of future risks. This increased uncertainty could cause both an increase in the cost of insurance and a decrease in its availability.[1]

---

[1] Counsel to the parties have consented to the filing of this brief. Letters of consent have been filed with the Clerk.

SUMMARY OF ARGUMENT

Rule 702 provides that if "scientific . . . knowledge" will assist the trier of fact, an expert may testify "thereto."[2] The language selected by the drafters underscores that the Rule authorizes testimony based only upon propositions that constitute "scientific . . . knowledge," not "scientific" speculation or conjecture. A proposition is not properly characterized as "scientific . . . knowledge" unless it is generally accepted within the scientific community. Thus, contrary to petitioners' position, the Federal Rules of Evidence exclude testimony based upon such unscientific disciplines as astrology, while permitting testimony based upon accepted scientific principles such as the law of gravity, even if the expert's case-specific opinions and conclusions based on such principles are not themselves generally accepted within the scientific community.

This reading of Rule 702 is confirmed by the structure of the Rules as well as by the common law principles that give content and context to what the drafters sought to achieve by the adoption of the Rules. Rule 702 sets forth an exception to the general rules of exclusion contained in Rules 602 and 802, which prohibit the introduction of testimony not based on personal knowledge and on hearsay. Expert testimony is an exception to the general rules that a witness' testimony must be based on personal knowledge and may not constitute hearsay. An expert witness testifying as to "scientific . . . knowledge" is expressing the accumulated learning and collective views of the relevant scientific discipline. Like other exceptions to these general rules of exclusion, Rule 702 requires an alternative showing of reliability before an exception will be granted admitting expert scientific testimony. This alternative showing is general acceptance within the scientific community of the scientific propositions and methodologies upon which the expert bases his testimony. Only then can

[2] For the convenience of the Court, we have set out relevant provisions of the Federal Rules of Evidence as an appendix to this brief.

the expert be said to be testifying to "scientific . . . knowledge," or basing his opinion thereon.

Moreover, Rule 702's focus on "scientific . . . knowledge" incorporates the common law approach to admission of scientific testimony reflected in *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923), and its progeny. The widespread judicial use of a general acceptance test prior to the adoption of the Federal Rules of Evidence provides further support for the proposition that Rule 702's use of the language "scientific . . . knowledge" necessitates continued use of such a test.

Failure effectively to enforce Rule 702's screening mechanism would adversely affect not only parties to federal litigation, but also the insurance industry as a whole. Abandonment of a screening mechanism for scientific testimony would expose the insurance industry to substantial, unexpected, and unfunded liability. If insurers are repeatedly subjected to liability for risks they did not assume, their inability to recoup the losses associated with this liability poses at least a potential threat to the financial health and stability of the insurance industry. Moreover, the absence of any threshold screening mechanism, when combined with more lenient, emerging damage theories, could overwhelm the insurance mechanism by rendering insurers unable to predict risks with necessary certainty.

ARGUMENT

I. THE FEDERAL RULES OF EVIDENCE REQUIRE THE EXCLUSION OF TESTIMONY BASED ON PROPOSITIONS NOT ACCEPTED IN THE SCIENTIFIC COMMUNITY

Petitioners devote a considerable portion of their brief to refuting the "contention that *Frye* survives as a judge-made rule for excluding evidence, merely because it existed for half a century prior to enactment of the Rules." Brief for Petitioners ("Pet. Br.") at 19-26. Specifically, petitioners argue that Rule 402—which declares that "all relevant evidence is admissible except as otherwise pro-

vided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority"—" 'wiped the slate clean' " and does not permit the adoption of "judge-made rules." *Id.* at 14.

This argument is a straw man. The question before the Court is not whether petitioners' expert testimony should be excluded by virtue of a "judge-made rule" that "stands independent of the Federal Rules." *Id.* at 18. Rather, the question before the Court is whether the Rules continue the common law practice—in "exist[ence] for half a century prior to enactment of the Rules"—of excluding scientific testimony that is not based on a scientific theory or methodology generally accepted within the scientific community. The short answer is that both the language and the structure of the Rules compel the conclusion that the Rules continue this practice.[3]

The general rule under the Federal Rules of Evidence is that "[a] witness may not testify to a matter unless . . . the witness has personal knowledge of the matter." Fed. R. Evid. 602. In addition, as a general matter, "[h]earsay is not admissible except as provided by these rules." Fed. R. Evid. 802. Article VII of the Rules, governing the admissibility of opinions and expert testimony, authorizes an important exception to these general rules for certain types of testimony by experts.[4] Absent Article VII, much of an

[3] Thus, petitioners' substantial reliance on *Bourjaily v. United States*, 483 U.S. 171 (1987), is misplaced. Petitioners rely on *Bourjaily* for the proposition that "this Court has refused to depart from the plain meaning of the Rules as a means of preserving pre-1975 common-law doctrines inconsistent with language in the Rules." Pet. Br. at 21. In this case, the Court need not "depart from the plain meaning of the Rules," but rather need only interpret the Rules as written. As shown below, it is petitioners' interpretation—that the Federal Rules of Evidence contain no standard for determining what constitutes "scientific . . . knowledge"—that is inconsistent with the language of the Rules.

[4] *See* Fed. R. Evid. 703 advisory committee's notes ("If it be feared that the enlargement of permissible data may tend to break down *the rules of exclusion* unduly, notice should be taken that the rule requires

expert's testimony would be inadmissible for lack of personal knowledge[5] or as hearsay.[6]

A. The Language of Rule 702 Imposes A Screening Mechanism

Rule 702, entitled "Testimony by Experts," sets forth the general exception to the personal knowledge and hearsay rules, authorizing "a witness qualified as an expert" to testify to "scientific, technical, or other specialized knowledge . . . in the form of an opinion or otherwise." Fed. R. Evid. 702. Before an expert will be permitted to testify to such "knowledge," however, Rule 702 requires that the proponent of the testimony establish the proper foundation for such testimony. Rule 702 provides in full:

that the facts or data 'be of a type reasonably relied upon by experts in the particular field.' ") (emphasis added).

[5] At common law, "the original and orthodox objection to 'mere opinion' was that it was the guess of a person who had no personal knowledge, and the 'mere opinion' of an expert was admitted as a necessary exception." 7 J. Wigmore, *Evidence in Trials at Common Law* § 1917, at 10 (J. Chadbourn ed. 1978). Indeed, Rule 602 itself confirms that the admissibility of expert testimony depends upon an exception to the general rule requiring personal knowledge. Rule 602 expressly states that "[t]his rule is subject to the provisions of rule 703, relating to opinion testimony by expert witnesses." Fed. R. Evid. 602.

[6] Although the rule against hearsay precludes a layman from testifying to "a fact which he has learned only by reading a medical or a mathematical book," an exception is made for "a professional physician or mathematician" testifying to such facts because an expert's reliance upon knowledge gained from such sources accords with "the accepted methods of professional work." 2 J. Wigmore, *Evidence in Trials at Common Law* § 665b, at 919 (J. Chadbourn ed. 1979); *see Pennsylvania Threshermen & Farmers Mut. Cas. Ins. Co. v. Messenger*, 181 Md. 295, 298, 29 A.2d 653, 655 (1943) (rejecting hearsay objection to expert's testimony based on "standard books, maps of recognized authority, or any other reliable sources"). Although there might be no hearsay objection if an expert testified solely on the basis of knowledge gained from personal experience, "[t]he knowledge of an expert in any science or art would be extremely limited if it extended no further than inferences from happenings within his own experience." *Messenger*, 181 Md. at 298, 29 A.2d at 655.

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

By its terms, Rule 702 thus requires the proponent of expert testimony to make at least three preliminary showings in order to establish the proper foundation. First, the proponent must establish that the expert will testify to "scientific, technical, or other specialized knowledge." Second, the proponent must demonstrate that such specialized knowledge "will assist the trier of fact to understand the evidence or to determine a fact in issue." Third, the proponent must establish that the witness is in fact "qualified as an expert by knowledge, skill, experience, training, or education" to testify to the specific body of knowledge relevant to the case.

The first of these preliminary showings bears most directly on the question presented in this case. Rule 702 refers to "scientific . . . knowledge," not to "scientific" speculation or conjecture. By employing this language, Rule 702 necessarily imposes some limits on the admissibility of expert testimony. Before admitting expert testimony, the trial court is required by Rule 702 to make a preliminary determination that the proposition to be espoused or applied by the expert does in fact constitute "scientific . . . knowledge." Of crucial importance, therefore, is what constitutes "scientific . . . knowledge."

According to one well-regarded dictionary, "KNOWLEDGE applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds." *Webster's Third New International Dictionary* 1252 (1976). That Rule 702 refers to "*scientific* . . . knowledge" is especially significant, given that the question presented in this case focuses on the proper

standard for admitting *scientific* testimony. Webster's defines "scientific" as "concerned with or treating of science," *id.* at 2032, and, in turn, defines "science" as "accumulated and *accepted knowledge* that has been systematized and formulated with reference to the discovery of *general truths* or the operation of general laws." *Id.* (emphasis added). Similarly, under the entry for "knowledge," Webster's states that the term "SCIENCE still sometimes interchanges with KNOWLEDGE but commonly applies to a body of systematized knowledge comprising facts carefully gathered and *general truths* carefully inferred from them, often underlying a practice, usu[ally] connoting exactness, and often denoting knowledge of unquestionable certainty." *Id.* at 1252 (emphasis added).

Thus, the language of Rule 702 necessarily imposes some requirement that the scientific propositions upon which an expert bases his testimony must be accepted as valid in the scientific community before they properly may be the subject of such expert testimony. Not every proposition relating to a given phenomenon will qualify as "scientific . . . knowledge." A novel and unsubstantiated claim does not become "scientific . . . knowledge" simply because the claim has been made by an individual trained in science. Rather, such a claim will attain the designation "scientific . . . knowledge," if at all, only after it is widely disseminated, scrutinized by fellow scientists, and commonly recognized as valid.[7] Claims regarding nuclear fission and cold fusion illustrate this point. Although nuclear fission was novel and controversial when first posited, it is today generally accepted as valid and employed in reactors through-

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[7] For example, whereas the proposition that each individual's fingerprints are unique qualifies as "scientific . . . knowledge," *see Piquett v. United States*, 81 F.2d 275 (7th Cir.), *cert. denied*, 298 U.S. 664 (1936), the proposition that the future may be predicted by astrology does not. *See Webster's Third New International Dictionary* 135 (1976) (defining "astrology" as "divination that treats of the supposed influences of the stars upon human affairs and of foretelling terrestrial events by their positions and aspects").

out the world.[8] Accordingly, propositions regarding nuclear fission are today properly referred to as "scientific . . . knowledge." Recent claims regarding cold fusion, by contrast, have not attained this status. Although widely disseminated and scrutinized, these claims have not been generally accepted as valid and hence are not properly described as "scientific . . . knowledge."[9]

Petitioners simply ignore Rule 702's use of the phrase "scientific . . . knowledge" and argue that the only inquiries required under Rule 702 are (1) whether specialized knowledge will assist the trier of fact, and (2) whether the witness is qualified as an expert in the specialized field. Pet. Br. at 30-31. This failure to come to grips with the language of Rule 702 is fatal to petitioners' argument. Petitioners' position is essentially that the Rules require the admission of expert "scientific" testimony without any inquiry into whether the underlying propositions are scientific. This interpretation would simply read the statutory language "scientific . . . knowledge" out of Rule 702.

Petitioners' position is inconsistent not only with the language of Rule 702, but also with the purpose and structure of the Rules and their common law background. As shown below, both the structure and the common law background of the Rules confirm that the general acceptance standard is the appropriate means for distinguishing "scientific . . . knowledge" from "scientific" speculation or or conjecture.

B. The Structure of the Federal Rules Confirm that Rule 702 Requires A Screening Mechanism

Rule 702's requirement that expert testimony be grounded in "scientific . . . knowledge" is not surprising

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[8] *See generally* M. Russell Wehr, *et al.*, *Physics of the Atom* (4th ed. 1984); Samuel Glasstone, *Sourcebook on Atomic Energy* (3d ed. 1979).

[9] *See* Andrew J. Pollack, *Cold Fusion, Derided in U.S., Is Hot in Japan*, N.Y. Times, Nov. 17, 1992, at C1 ("To be sure, the level of interest in cold fusion should not be exaggerated. In Japan, as in the United States, 'most scientists don't believe it,' said Makoto Okamoto, a professor at the Tokyo Institute of Technology who is working in the field.").

given the structure of the Rules. Rule 702 is an exception to the hearsay rule and the rule requiring personal knowledge. Testimony about "scientific . . . knowledge" is nothing more than testimony about the views of the relevant scientific community. As one commentator has explained:

> An expert scientific witness is not admitted to testify to his or her personal beliefs and opinions; rather, the philosophy of expert testimony is that science itself is testifying through a particular expositor of a discipline. The only proper focus of an expert witness, therefore, is on the collective views of a scientific discipline as perceived by a person trained in the methods and conclusions of that discipline.

Donald Elliott, *Toward Incentive-Based Procedure: Three Approaches for Regulating Scientific Evidence*, 69 B.U. L. Rev. 487, 498-99 (1989) (hereinafter "*Incentive-Based Procedure*").

Rule 702 authorizes the expert to summarize or restate "the collective views of a scientific discipline" only because those views have achieved the status of "scientific . . . knowledge." Without Rule 702, such testimony would be inadmissible. Although Rule 402 provides that the general rule is that all relevant evidence is admissible, it qualifies this general rule with the phrase "except as otherwise provided . . . by these rules." As noted, Rules 602 and 802 provide "otherwise" when the witness lacks personal knowledge or is testifying to hearsay. Expert testimony about "scientific . . . knowledge" is necessarily testimony that consists largely of statements based on other than personal knowledge and restatements of the views of out-of-court declarants. Thus, but for Rule 702, such testimony would be inadmissible. The requirement reflected in the language of Rule 702—that the expert's testimony must be based upon "scientific . . . knowledge"—provides the reliability safeguard that justifies admission of such testimony into evidence as an exception to the general rules of exclusion set forth in Rules 602 and 802.

This understanding of Rule 702 is consistent with other provisions of the Rules that serve a similar function. In particular, the Rules provide for several alternative means of supplying "scientific . . . knowledge" to assist the trier of fact, each of which requires a showing of reliability as a prerequisite to its use. In addition, Rule 703, which facilitates the admission of expert opinion testimony authorized generally by Rule 702, also imposes a reliability requirement.

1. Rule 702 Must Be Read *In Pari Materia* with Rules 803(18) and 201

As the Advisory Committee Notes explain: "An intelligent evaluation of facts is often difficult or impossible without the application of some scientific, technical, or other specialized knowledge. The most common source of this knowledge is the expert witness, although there are other techniques for supplying it." Fed. R. Evid. 702 advisory committee's notes. The only "other techniques" available under the Rules for supplying "scientific, technical, or other specialized knowledge" are the learned treatise exception to the hearsay rule under Rule 803(18) and judicial notice under Rule 201. These techniques require that the proponent establish that the scientific knowledge in question be set forth in "a reliable authority," Fed. R. Evid. 803(18), or be "one not subject to reasonable dispute." Fed. R. Evid. 201.

The first of these methods is the learned treatise exception to the hearsay rule. Rule 803(18) provides an exception for the following:

> To the extent called to the attention of an expert witness upon cross-examination or relied upon by the expert witness in direct examination, statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. If admitted, the statements may be read into evidence but may not be received as exhibits.

Fed. R. Evid. 803(18). By its terms, the Rule authorizes the admission of "statements contained in published treatises, periodicals, or pamphlets on a subject of . . . science" only if such "treatises, periodicals, or pamphlets" are (1) "published," and (2) "established as a reliable authority."

The publication requirement significantly enhances the general reliability of sources of scientific knowledge. As the Advisory Committee Notes recognize, "a high standard of accuracy is engendered [in the case of a learned treatise] by various factors: the treatise is written primarily and impartially for professionals, subject to scrutiny and exposure for inaccuracy with the reputation of the writer at stake." Fed. R. Evid. 803(18) advisory committee notes. The second requirement, that the treatise in question be "established as a reliable authority," provides an additional and case-specific assurance of reliability. This requirement calls upon the judge to make a preliminary determination either based on the testimony of experts in the field or by judicial notice.

The second method for supplying "scientific . . . knowledge" in a case is by means of judicial notice. Judicial notice of "adjudicative facts" is permitted if such facts are "not subject to reasonable dispute" in that they are "generally known" or are "capable of accurate and ready determination." Fed. R. Evid. 201. The Advisory Committee Notes state that while "[t]he usual method of establishing adjudicative facts is through the introduction of evidence, ordinarily consisting of the testimony of witnesses," "[i]f particular facts are outside of reasonable controversy, this process is dispensed with as unnecessary. *A high degree of indisputability is the essential prerequisite.*" Fed. R. Evid. 201 advisory committee notes (emphasis added). Hence, scientific propositions not subject to reasonable dispute—such as the law of gravity—may be the subject of judicial notice.[10]

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[10] The only potential basis for distinguishing among the three methods

Under the Federal Rules of Evidence, testimony concerning scientific knowledge is generally inadmissible under the personal knowledge requirement and the rule against hearsay. The purpose of these rules is to exclude unreliable testimony. *See* Fed. R. Evid. 602 advisory committee's notes (the personal knowledge requirement is a " 'manifestation' of the common law insistence upon the 'most reliable sources of information' "); Fed. R. Evid. Article VIII advisory committee's notes ("The solution evolved by the common law [to the conflict between the goal of admitting only the best evidence and the necessity of admitting some hearsay] has been a general rule excluding hearsay but subject to numerous exceptions under circumstances supposed to furnish guarantees of trustworthiness.") (introductory note). Predictably, then, the exceptions to the general rule of exclusion—such as Rules 201 and 803(18)—require indicia of reliability as a prerequisite to admission.[11]

Petitioners' suggestion that the drafters of Rule 702 failed to adopt a comparable reliability standard governing the admission of "scientific . . . knowledge" when offered through expert testimony is without merit. Like Rules 201

of supplying "scientific . . . knowledge" is that propositions judicially noticed are accepted as conclusive in civil matters. Accordingly, although all three impose similar requirements it is not surprising that the standard for judicial notice is higher than the standard for the admission of "scientific . . . knowledge" through expert testimony or learned treatises. Whereas judicial notice requires "indisputability," Fed. R. Evid. 201 advisory committee's notes, the learned treatise exception requires only that the text be "established as a reliable authority," Fed. R. Evid. 803(18), and the expert testimony exception requires only that the propositions upon which such testimony rests qualify as "scientific . . . knowledge." Fed. R. Evid. 702. In the case of the latter methods, "scientific . . . knowledge" can be admitted even though some in the scientific community dispute either the reliability of the treatise or the validity of the proposition presented by the expert. All that is required is general reliability or acceptance, not indisputability.

[11] Courts make preliminary determinations regarding the applicability of exceptions to rules of exclusion under Rule 104 (a). *See Bourjaily*, 483 U.S. at 171 (applying Rule 104(a) to determine the applicability of the co-conspirator exception to the rule against hearsay).

and 803(18), Rule 702—which provides for the admission of expert testimony based on "scientific . . . knowledge"—constitutes an exception to the Federal Rules' general exclusion of testimony based upon hearsay or a lack of personal knowledge. The Notes to Rule 702 suggest that the learned treatise exception and the judicial notice mechanism are means of "supplying" "scientific . . . knowledge" in lieu of the method set forth in Rule 702. In light of the strictures of these alternative means, it is patently unreasonable to suggest—as petitioners do—that Rule 702 may be read to permit the admission of any proposition that an expert is willing to label "scientific . . . knowledge" with no comparable authority on the part of the court to make a preliminary inquiry into reliability.[12]

Rather, Rules 201, 702, and 803(18) must be read *in pari materia*. As the Reporter for the Advisory Committee that drafted the Rules, Edward W. Cleary, has stated:

> Familiar doctrine requires that statutes be read as a whole. Similarly as to the Rules, which must not be read separately and in isolation but as a part of an entire system, with due regard to its plan and organization and to the contents of rules other than the particular one under consideration.

Edward W. Cleary, *Preliminary Notes on Reading the Rules of Evidence*, 57 Neb. L. Rev. 908, 917 (1978) (footnote omitted).[13] Both the learned treatise exception and judicial notice rule dispense with the requirements of per-

[12] It is important to stress that the preliminary inquiry into reliability embodied in Rule 702's "scientific . . . knowledge" requirement relates only to the scientific propositions and methodologies utilized by experts in forming case-specific opinions and conclusions, not to the opinions and conclusions themselves. Thus, it is the scientific propositions and methodologies underlying an expert's opinion, not the opinion itself, that must be generally accepted within the scientific community. *Cf. Barefoot v. Estelle*, 463 U.S. 880 (1983) (upholding admission of experts' case-specific psychiatric predictions against constitutional challenge to their reliability).

[13] This Court quoted this article approvingly in its unanimous decision in *United States v. Abel*, 469 U.S. 45, 51-52 (1984).

sonal knowledge and in-court statements.[14] Rule 702 is an alternative means of avoiding these same requirements. Under Rule 702, "a witness qualified as an expert" is permitted to testify concerning helpful "scientific, technical, or other specialized knowledge" notwithstanding the general rule against hearsay and the rule requiring personal knowledge.

Whether "scientific . . . knowledge" is admitted via judicial notice, expert testimony, or a learned treatise, generally such knowledge remains hearsay and is based on other than personal knowledge. Thus, it is to be expected that all three methods of introducing otherwise inadmissible evidence would require similar assurances of trustworthiness before an exception would be made admitting such evidence.[15]

2. Rule 702 Must Be Read *In Pari Materia* With Rule 703

As discussed, Rule 702 provides an exception to the general rules of exclusion and thus permits an expert to testify about propositions of "scientific . . . knowledge . . . in the form of an opinion or otherwise." Fed. R. Evid. 702. The meaning of the phrase "in the form of an opinion or otherwise" is explained by the Advisory Committee Notes to Rule 702. According to the Notes, an expert's testimony about "scientific . . . knowledge" may take one

[14] It has been suggested that the functions of the hearsay and personal knowledge requirements are largely interchangeable. *See* Maguire, *Evidence: Common Sense and Common Law* 23-27 (1947).

[15] This conclusion is supported not only by the specific exception to the hearsay rule for learned treatises, but also by the fact that all exceptions to the hearsay rule are based on the presence of substitute indicia of reliability. Fed. R. Evid. Article VIII advisory committee's introductory notes ("The solution evolved by the common law has been a general rule excluding hearsay but subject to numerous exceptions under circumstances supposed to furnish guarantees of trustworthiness."). *See* Fed. R. Evid. 803(24), 804(b)(5) (setting forth catch-all exceptions to the hearsay rule for statements "not specifically covered by any of the foregoing exceptions but having equivalent circumstantial guarantees of trustworthiness").

of two forms. First, Rule 702 authorizes an expert to give "a dissertation or exposition of scientific or other principles relevant to the case, leaving the trier of fact to apply them to the facts." Fed. R. Evid. 702 advisory committee's notes (hereinafter "dissertation" testimony). Second, Rule 702 makes it possible for an expert to give an opinion "suggesting the inference which should be drawn from applying the specialized knowledge to the facts." *Id.* (hereinafter "opinion" or "application" testimony).[16]

This second or "opinion" type of testimony, however, is not automatically admissible by virtue of Rule 702 alone. Although Rule 702 removes any hearsay or personal knowledge objection to the expert's use of, or reference to, general propositions of "scientific . . . knowledge" in rendering an opinion, additional rules (Rules 703 through 705) are necessary to remove remaining barriers to the admission of such opinion testimony. As the Advisory Committee Notes explain:

> The use of opinions is not abolished by the rule, however. It will continue to be permissible for the experts to take the further step of suggesting

[16] As used in Rule 702, the term "opinion" refers to the inference to be drawn from the *application* of scientific or other specialized knowledge to the facts of the case:

> Most of the literature assumes that experts testify only in the form of opinions. The assumption is logically unfounded. The rule accordingly recognizes that an expert on the stand may give a dissertation or exposition of scientific or other principles relevant to the case, leaving the trier of fact to apply them to the facts. . . . [I]t seems wise to recognize that opinions are not indispensable and to encourage the use of expert testimony in non-opinion form when counsel believes the trier can itself draw the requisite inference. The use of *opinions* is not abolished by the rule, however. It will continue to be permissible for the experts to take the further step of suggesting the inference which should be drawn from *applying* the specialized knowledge to the facts. See Rules 703 to 705.

Fed. R. Evid. 702 advisory committee's note (emphasis added).

> the inference which should be drawn from applying the specialized knowledge to the facts. See Rules 703 to 705.

Fed. R. Evid. 702 advisory committee's note.

Rule 703 provides that the facts or data upon which an expert bases an opinion or inference need not be admissible in evidence "[i]f of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Rule 704 generally eliminates the objection to the introduction of opinion testimony that "embraces an ultimate issue to be decided by the trier of fact." Rule 705 authorizes an expert to "testify in terms of an opinion or inference and give reasons therefor without prior disclosure of the underlying facts or data."

Rule 703 is of particular relevance to the question before the Court. By authorizing a hearsay exception for the specific facts underlying the expert's opinion only "[i]f of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject," Rule 703 imposes a reliability requirement analogous to those imposed by Rules 201, 702, and 803(18). The latter rules make it possible for an expert to recite or rely upon general propositions of "scientific . . . knowledge" that would otherwise be inadmissible. Rule 703 supplements the exception contained in Rule 702 by providing a further exception for case-specific facts or data upon which the expert must also rely when giving a case-specific opinion.

Thus, when read together, Rules 702 and 703 permit an expert to render an opinion based both upon general propositions of "scientific . . . knowledge" and upon facts or data specific to the case.[17] It is patently unreasonable

[17] Petitioners rely on this Court's decision in *Barefoot v. Estelle*, 463 U.S. 880 (1983)—upholding the admission of expert opinions regarding future dangerousness—for the proposition that the "ultimate safeguard" is not the exclusion of such opinion testimony, but rather admission of the testimony subject to vigorous cross-examination and rebuttal. Pet. Br. at 39-40. Petitioners misread this Court's decision in *Barefoot*. In *Barefoot*, the Court rejected a *constitutional* challenge to the admission of expert opinions that concluded that the defendant "would probably commit further acts of violence and represent a continuing threat to society." 463 U.S. at 884. The defendant did not argue that the experts' conclusions were not based on "scientific . . . knowledge." Thus, the Court had no occasion to consider whether there exist generally accepted principles of psychiatry that can be applied to predict an individual's future dangerousness—the only question that would be relevant under Rule 702. Rather, the Court rejected the defendant's argument that "psychiatrists, individually and as a group, are incompetent to predict with an acceptable degree of reliability that a particular criminal will commit other crimes in the future." *Id.* at 896.

In addition, the Court rejected the defendant's alternative argument—that "psychiatrists should not be permitted to testify about future dangerousness in response to hypothetical questions and without having examined the defendant personally," *id.*—on the ground that the longstanding practice of medical professionals has been to give opinions " 'in cases where they have not themselves seen the patient, and have only heard the symptoms and particulars of his state detailed by other witnesses at the trial.' " *Id.* at 903 (quoting *Spring Co. v. Edgar*, 99 U.S. 645, 657 (1879)). Thus, although the Court's holding was not based explicitly on Rule 703, the Court's holding was consistent with that Rule. *See id.* at 904.

to suggest that although Rule 703 requires that the specific facts or data upon which the expert bases his opinion be "of a type reasonably relied upon by experts in the particular field," Rule 702 permits the expert to base that same opinion on general scientific propositions that have not been accepted in the field. Thus, Rules 702 and 703 must be read as part of a coherent whole, requiring similar indicia of reliability before an expert will be permitted to give an opinion based on either the facts specific to the case or the general scientific propositions applicable to those facts.

C. The Common Law Background Supports Respondent's Interpretation of Rule 702

As this Court stressed in *United States v. Abel*, 469 U.S. 45 (1984), the Federal Rules of Evidence must be read in light of the common law principles in existence prior to the adoption of the Rules. In *Abel*, the Court held that the Rules continue to permit the longstanding common law

practice of impeachment for bias. In so holding, the Court noted:

> In principle, under the Federal Rules no common law of evidence remains. "All relevant evidence is admissible, except as otherwise provided. . . ." In reality, of course, the body of common law knowledge continues to exist, though in the somewhat altered form of a source of guidance in the exercise of delegated powers.

Abel, 469 U.S. at 51-52 (quoting Cleary, *Preliminary Notes*, 57 Neb. L. Rev. at 915 (1978) (footnote omitted)). Accordingly, although the Rules are silent on the question, the Court in *Abel* concluded, "we think it unlikely that they [the drafters of the Federal Rules of Evidence] intended to scuttle entirely" the evidentiary doctrine of impeachment for bias that was "in accord with the overwhelming state of authority" at the time the Rules were drafted. *Id.* at 50.

It is even more unlikely that the drafters of the Rules intended to eliminate the widely-recognized requirement that expert scientific testimony must be based upon propositions generally accepted within the scientific community. As petitioners concede, the general acceptance requirement has been in "exist[ence] for half a century prior to enactment of the Rules." Pet. Br. at 19. By requiring that scientific testimony be based on a "scientific principle . . . sufficiently established to have gained general acceptance in the particular field in which it belongs," the judge-made rule announced in *Frye* had both the purpose and effect of ensuring that scientific testimony would be based solely on "scientific . . . knowledge." In addition, unlike the evidentiary rule in *Abel*, the general acceptance requirement has support in the language of the Rules themselves. The drafters' use of the phrase "scientific . . . knowledge" in Rule 702 persuasively demonstrates that they did not intend to abandon the common law limitation on scientific testimony.[18]

[18] Petitioners attempt to draw a distinction between common law rules of "*inclusion*" and "*exclusion*," and suggest that *Abel* rests upon this distinction. Pet. Br. at 24 n.49. Specifically, petitioners assert that Rule 402 creates "a presumption of admissibility," and that "Rule 402 demonstrates that unless Congress preserved or authorized a common-law *exclusion* doctrine in *a specific Rule*, the doctrine cannot be used to exclude evidence." *Id.* Petitioners misperceive the nature of Rule 702. That Rule is not a rule of *exclusion*, but, as previously explained, is an *exception* to rules of exclusion set forth in Rules 602 and 802—the rule against hearsay and the rule requiring personal knowledge, respectively. Therefore, respondent need not, as petitioners suggest, establish that Rule 702 *excludes* the expert testimony proffered by petitioners. Rather, the burden is on the petitioners to demonstrate that the testimony they wish to introduce falls within Rule 702's limited exception to the general rules excluding such testimony. Petitioners have made no attempt to meet this burden.

It is unlikely that the drafters of the Rules would have effected such a radical departure from this common law practice without some mention. The silence on this point stands in marked contrast to the clear announcements made by the drafters when the Rules adopt evidentiary principles that change accepted common law practice. *See, e.g.*, Fed. R. Evid. 408 advisory committee's notes (noting that Rule 408 expands common law rule to exclude not only offers of compromise themselves but also "evidence of conduct or statements made in compromise negotiations"); Fed. R. Evid. 601 advisory committee's notes (noting that Rule 601 eliminates common law rules of incompetency such as "religious belief, conviction of crime, and connection with the litigation as a party or interested person or spouse of a party or interested person").

II. RULE 702 REQUIRES SCREENING OF UNDERLYING SCIENTIFIC PROPOSITIONS RATHER THAN SCREENING OF CONCLUSIONS DERIVED FROM THE APPLICATION OF THOSE PROPOSITIONS

Although the "scientific . . . knowledge" standard of Rule 702 means that the expert's testimony must proceed from propositions or methodologies generally accepted within the scientific community, it does not mean that the expert's *conclusions* must themselves be generally accepted within the scientific community. This fallacy underlies much

of the argumentation set forth in the petitioners' brief and in those of their supporting *amicii*. *See* Pet. Br. at 32.

A. The Ninth Circuit Correctly Applied a Bright-Line Rule in the Case Below

In affirming the district court's exclusion of petitioners' expert testimony, the Ninth Circuit did not hold that the conclusion reached by the expert was inadmissible. Rather, the court correctly focused on whether the methodology underlying the experts' testimony had been accepted within the scientific community. As the court below stated: "For expert opinion based on a given scientific methodology to be admissible, the methodology cannot diverge significantly from the procedures accepted by recognized authorities in the field." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128, 1130 (9th Cir. 1991); Joint Appendix ("J.A.") at 239. In this case, the court concluded that the methodology underlying the experts' testimony diverged from accepted methodology.

While recognizing that, if properly conducted, the scientific technique in issue—reanalysis of epidemiological studies—is accepted within the scientific community, the court found that the reanalysis undertaken by petitioners' expert in this case did not comply with the necessary safeguards. The scientific community holds that an integral part of any acceptable reanalysis is publication and peer review. *See id.* at 1131; J.A. at 240 (citing Michael Dore, *A Commentary on the Use of Epidemiological Evidence in Demonstrating Cause-in-Fact*, 7 Harv. Envtl. L. Rev. 429, 438-39 (1983)). Accordingly, the court found that reanalysis is generally accepted "only when it is subjected to verification and scrutiny by others in the field." *Id.* Because the reanalysis performed by petitioners' expert did not follow this method, the court found that the expert's opinion did not fall within the exception for testimony based on accepted scientific techniques.

Petitioners complain that the Ninth Circuit's requirement that their experts comply with accepted scientific methodologies constituted an improper delegation of the

power to determine the admissibility of the experts' testimony. Pet Br. at 47-48. Far from constituting an abdication of its responsibilities under Rule 702, the Ninth Circuit's insistence upon compliance with accepted scientific techniques was necessary to enforce the "scientific . . . knowledge" requirement of that Rule. Petitioners' position is that no showing of reliability need be made at the outset because whether or not expert testimony is based on scientific knowledge goes only to the weight not to the admissibility of such testimony. Pet. Br. at 39. This argument ignores the point that expert testimony as to "scientific . . . knowledge" fails the personal knowledge and hearsay requirements of the Rules and thus is inadmissible unless it falls within the limited exception set forth in Rule 702. That Rule, like all other exceptions to the hearsay rule, requires a threshold showing of reliability before otherwise inadmissible evidence can be admitted. Neither in the courts below nor in this Court have petitioners made any attempt to justify the creation of any additional exceptions to the hearsay and personal knowledge rules that would warrant admission of their expert's testimony in this case.

B. Other Courts Have Applied a Bright-Line Rule Under Rule 702

The Ninth Circuit is not alone in insisting that expert testimony must, at a minimum, be based on generally accepted scientific theories and procedures. As the Sixth Circuit recently reaffirmed, "[f]or expert testimony to be admissible under Rule 702, . . . a qualified expert . . . [must be] testifying on a proper subject . . . *in conformity to a generally accepted explanatory theory*." *United States v. Kozminski*, 821 F.2d 1186, 1194 (6th Cir. 1987) (en banc) (emphasis in original). The application of this straight-forward test is well illustrated by the Sixth Circuit's earlier decision in *United States v. Brown*, 557 F.2d 541 (6th Cir. 1977). There, the court considered the admissibility of expert testimony offered by the government to link the defendant to the crime. The expert in *Brown* proposed to use ion micropropic analysis to opine that a hair sample found at the scene of the crime and a hair sample taken

from the defendant "were of common origin." *Id.* at 555. Although ion micropropic analysis had been accepted within the scientific community to compare samples of "metals and inorganic materials," *id.*, the use of this technique to compare organic materials (such as hair) had not been.[19] Thus, the court concluded that "the government failed to fulfill the threshold requirement of demonstrating that ion micropropic analysis is a generally accepted procedure for comparing samples of human hair." *Id.* at 557.[20]

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[19] Although a particular scientific technique may be generally accepted for some purposes, it may not be generally accepted for others. Thus, petitioners' assertion that the FDA and the EPA rely on animal studies in assessing causation is true, but irrelevant. Pet. Br. at 5. The FDA's charge is to safeguard the population from exposure to potential risks, even if slight, not to act only when causation can be proven.

Moreover, although reliance on *in vivo* and *in vitro* animal studies may be generally accepted in the absence of human epidemiological studies to make a cross-species prediction of whether a particular substance is a human teratogen, it does not appear—nor have petitioners demonstrated—that the use of animal studies is generally accepted to contradict more reliable human studies uniformly replicating a finding to the contrary. *See In re Agent Orange Prod. Liab. Litig.*, 611 F. Supp. 1223, 1231 (E.D.N.Y. 1985) (Human epidemiological studies "are the only useful studies having any bearing on causation. All the other data supplied by the parties rests on surmise and inapposite extrapolations from animal studies. . . ."), *aff'd* 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988). For example, although a positive result from the multiple-puncture tuberculous ("TB") test is generally accepted as a means of alerting doctors to the possibility that a patient has TB, it is not generally accepted as an appropriate means of diagnosing TB in the face of a contrary indication from the more reliable intracutaneous PPD test, which is administered to confirm or refute the results of the multiple-puncture test. *See* 1 *Harrison's Principles of Internal Medicine* 642 (12th ed. 1991) (multiple-puncture tests "can be recommended only as screening tests, and positive tests should be repeated using intracutaneous PPD").

[20] The court was careful to note that conflicting "conclusions drawn by experts, so long as they are based on generally accepted and reliable scientific principle," are ordinarily admissible. *Id.* at 556. Thus, the court suggested that had the expert employed the generally accepted neutron activation analysis to conclude that the hair samples were of common origin, the expert's testimony would have been admissible. *Id.* at 557-58.

The Eighth Circuit has also applied this bright-line test. In *United States v. Two Bulls*, 918 F.2d 56 (8th Cir. 1990), the court vacated and remanded a conviction based in part on expert testimony employing deoxyribonucleic acid ("DNA") profiling to link the defendant to a crime. Although the court observed that the theory underlying DNA profiling was generally accepted within the scientific community, it found that the district court erred in failing to determine whether there was agreement within the scientific community concerning the proper methods for conducting DNA profiling and whether such methods were employed in this case.

Significantly, the court found that Rule 702 and the common law *Frye* test imposed essentially interchangeable requirements, noting that "both require the same general approach to the admissibility of new scientific evidence. Neither rule should permit speculative and conjectural testing which fails normal foundational requirements necessary for the admissibility of scientific testimony or opinion." *Id.* at 60. Accordingly, the court remanded the case for the district court with instructions to hold an expanded pretrial hearing to inquire into these matters prior to admitting the expert's testimony. *Id.* at 61.

Subsequently, in *United States v. Jakobetz*, 955 F.2d 786 (2d Cir.), *cert. denied*, 113 S. Ct. 104 (1992), the Second Circuit affirmed a conviction that rested in part on the introduction of DNA profile evidence. Although the district court stated that it was applying the Second Circuit's earlier modification of the *Frye* test, the Second Circuit noted that the lower court's analysis would satisfy both the *Frye* test and the *Two Bulls* standard. *Id.* at 799. Specifically, the district court found that "the general theories of genetics which support DNA profiling are unanimously accepted within the scientific community," that "the specific techniques used by the FBI . . . are commonly used by scientists in microbiology and genetics research," and that "the FBI had adhered to strict scientific protocol in their testing of the DNA samples in this case." *Id.* at 798-99 (citations omitted).

III. FAILURE TO APPLY RULE 702's SCREENING REQUIREMENT THREATENS TO UNDERMINE THE INSURANCE MECHANISM

If this Court fails to enforce the "scientific . . . knowledge" requirement of Rule 702, several adverse consequences could follow. First, insurers could be held liable under existing policies for risks they did not assume and for which no premium was collected. This, in turn, could undermine their financial condition and hamper their ability to serve the on-going insurance needs of millions of individuals and businesses. Second, failure to enforce Rule 702's "scientific . . . knowledge" requirement, combined with speculative damage theories will create uncertainty in underwriting prospective policies covering future occurrences. As a result, insurance could become more expensive and less available to many businesses.

A. Abandonment of Rule 702's Screening Mechanism Would Result in Unanticipated Losses which Could Adversely Affect Insurers' Financial Condition

Liability insurance provides policyholders with protection against third party claims or suits. Even if a claim or suit is unsuccessful, the insurance company expends time and money for its investigation and defense. If the insured entity settles the claim or is held liable for damages, the insurer also makes indemnity payments consistent with the terms of the policy. Roland H. Long, 1 *The Law of Liability Insurance* § 1.01[1], at 1-2; § 1.03[4], at 1-12, 1-13 (1992).

In underwriting liability coverage, the insurer must make certain judgments regarding the riskiness of the activity to be engaged in by the insured. These judgments must include an estimate not only of the physical exposures associated with the insured's activity but also of the relevant legal exposures—*i.e.*, the likelihood that a judge or jury will find the insured liable for tort damages. Robert B. Holtom, *Underwriting: Principles & Practices* 235 (3d ed. 1987). Given changing legal standards regarding negligence and strict liability, particularly with respect to toxic

tort liability,[21] these assessments are extremely difficult to make; however, reliance on accepted scientific principles provides some guidance. For example, underwriters may now assume with some confidence that claims for traumatic cancer, where a blow or a cut is alleged to cause a cancerous growth, can be excluded from their estimation of risk. *Compare Canon Reliance Coal Co. v. Industrial Commission*, 211 P. 868 (Colo. 1922) (upholding finding that being hit with a piece of coal caused cancer), *with Tonkovich v. Department of Labor & Industries of State*, 195 P.2d 638 (Wash. 1948) (overturning a jury finding that broken foot caused cancer). If, however, policyholders are to be held liable not on the basis of "scientific . . . knowledge," but on the basis of propositions that have no foundation in generally accepted scientific truths, then the insurer can have no confidence in its underwriting judgments, either retrospectively or prospectively.

If this Court finds that Rule 702 permits the introduction of scientific testimony based on unaccepted scientific propositions, insurers will incur liability that they could not reasonably have anticipated, and which was not reflected in the premiums they charged, at the time existing coverage was underwritten. This problem is compounded by the fact that a long period of time may elapse between the time a policy is underwritten and the time a claim is made and eventually tried. For example, as this case demonstrates, an insurer who provided coverage to the manufacturer of bendectin while it was on the market from 1956 to 1983 would still be facing potential liability today,

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[21] *See generally Liability: Perspectives and Policy* 1-16 (R. Litan & C. Winston ed., 1988) (detailing liberalization of the tort system). For example, some courts have recently imposed liability based on a plaintiff's "fear of cancer," dispensing with any requirement that the plaintiff prove actual injury or causation. *See* Elliott, *Incentive-Based Procedures*, 69 B.U. L. Rev. at 491 n.19 (noting that the Fifth Circuit "upheld an award for a plaintiff's fear of getting cancer even though there was no proof of a 'medical probability' that he would actually develop the disease.") (citing *Dartez v. Fibreboard* Corp., 765 F.2d 456, 468 (5th Cir. 1985)).

more than a decade after the original estimate of risk was made. If, in the interim, a court abandons the traditional standard upon which scientific testimony is permitted to be introduced, insurers will suffer significant unanticipated losses. Given the requirements of state rating laws and the highly competitive nature of the insurance market, companies typically will not be able to recoup these losses by increasing future premiums. *See* U.S. Dep't. of Justice, Tort Policy Working Group, *An Update on the Liability Crisis*, app. at 11 (1987) (hereinafter "*DOJ Update*"). If insurers are repeatedly subject to liability for risks they did not assume, their inability to recoup the losses associated with this liability poses at least a potential threat to the financial health and stability of the insurance industry. Moreover, given premium/surplus requirements, unexpected liability could adversely affect the very ability of insurers to provide coverage in the future. *See DOJ Update* app. at 11 n. 19 ("Unless new capital can flow easily into the industry, such accumulated losses may deplete reserves and, in the presence of solvency regulation or other constraints on the ratio of premiums to reserves, contribute to a supply problem, at least in the short run.").

B. The Interplay Between a Lenient Threshold for the Admissibility of "Scientific" Testimony and Toxic Tort Damage Theories Could Overwhelm the Insurance Mechanism

This Court's enforcement of Rule 702's "scientific . . . knowledge" requirement will create some degree of predictability in the murkiest area of the nation's tort law. While the screening mechanism potentially regulates the admission of expert testimony in all tort actions, it is in the area of litigation stemming from exposure to possibly hazardous substances—commonly referred to as toxic torts—that the absence of a screening mechanism would have the most profound and harmful impact. A menu of emerging damage theories, including enhanced risk of future harm, mental anguish, immunotoxicity, and medical monitoring, is available to the toxic tort claimant. In many instances, all of these damage theories are alleged by

plaintiffs in a single action. The union of these novel damage theories with a lenient test for admissibility of questionable scientific testimony would lengthen the causal chain beyond the reach of established tort law principles and create a new class of claims and claimants.

In authorizing a novel damage theory, a legislature or a common law court makes the determination that liability is properly imposed under a particular set of circumstances. This does not mean, however, that courts should go further and permit recovery under these novel theories when the requisite elements of these causes of action cannot be proven. For example, some states now permit a cause of action for enhanced risk of future harm, which typically requires a showing that the plaintiff has been exposed to a substance that makes it more probable than not that the plaintiff will be afflicted with a certain illness in the future. *See In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990), *cert. denied*, 111 S. Ct. 1584 (1991). While this cause of action certainly makes it easier for plaintiffs to recover, it still requires the plaintiff to prove a probability of causation. Under petitioners' reading of the Federal Rules, a jury would be permitted to award damages even in the absence of any evidence of causation based on accepted principles of scientific knowledge.

The interplay between the reduced threshold of admissibility of questionable scientific testimony and attenuated toxic tort theories could overwhelm the insurance mechanism. Insurance can only function where insurance companies are able to spread the cost of the risks they insure over a large number of policyholders. To do this, however, there must be some degree of certainty with which the risks can be predicted. *New Castle County v. Hartford Accident & Indemnity Co.*, 970 F.2d 1267, 1272 (3d Cir. 1992) ("insurers will only underwrite a certain, specific risk, calculable to a margin of actuarial certainty"). "Serious practical problems face insurers in handling insurance against potentially wide, open-ended liability. From an insurer's point of view it is not practical to cover, without limit, a liability that may reach catastrophic proportions,

or to fix a reasonable premium on a risk that does not lend itself to actuarial measurement or estimate." Fowler V. Harper, Fleming James, Oscar S. Gray, 4 *The Law of Torts* § 25.18C at 634 (1986).

Even if insurers were somehow able to underwrite these risks, carriers would be forced to increase premiums to take into account this new risk and to satisfy the increased number of claims. Corporate policyholders are not the ones that would ultimately bear the increased costs. The cost would be passed on to society, either through price increases on products and services or through cutbacks in other areas, such as numbers of employees. *See Amaya v. Home Ice, Fuel & Supply Co.*, 59 Cal. 2d 295, 314 (1963) (when courts impose liability, society as a whole is affected "in the form of the cost of insurance."); *Borer v. American Airlines, Inc.*, 19 Cal. 3d 441, 447 (1977) ("Realistically the burden of payment of awards . . . must be borne by the public generally in increased insurance premiums or, otherwise, in the enhanced danger that accrues from the greater number of people who may choose to go without any insurance."). Unfortunately, but inevitably, increased premiums that would follow from the union of a lenient admissibility standard with novel toxic tort damage theories would "especially hurt small and medium-sized businesses." Willmore, *In Fear of Cancerphobia*, 3 Toxics L. Rep. (BNA) 559, 563 (Sept. 28, 1988).

CONCLUSION

For the foregoing reasons, the judgment of the Ninth Circuit Court of Appeals should be affirmed.

Respectfully submitted,

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APPENDIX

APPENDIX

(Federal Rules of Evidence)

Rule 104. Preliminary Questions

(a) **Questions of admissibility generally.** Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

Rule 201. Judicial Notice of Adjudicative Facts

(a) **Scope of rule.** This rule governs only judicial notice of adjudicative facts.

(b) **Kinds of facts.** A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.

(c) **When discretionary.** A court may take judicial notice, whether requested or not.

(d) **When mandatory.** A court shall take judicial notice if requested by a party and supplied with the necessary information.

(e) **Opportunity to be heard.** A party is entitled upon timely request to an opportunity to be heard as to the propriety of taking judicial notice and the tenor of the matter noticed. In the absence of prior notification, the request may be made after judicial notice has been taken.

(f) **Time of taking notice.** Judicial notice may be taken at any stage of the proceeding.

(g) **Instructing jury.** In a civil action or proceeding, the court shall instruct the jury to accept as conclusive any fact judicially noticed. In a criminal case, the court shall

instruct the jury that it may, but is not required to, accept as conclusive any fact judicially noticed.

Rule 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible

All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Rule 602. Lack of Personal Knowledge

A witness may not testify to a matter unless evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter. Evidence to prove personal knowledge may, but need not, consist of the witness' own testimony. This rule is subject to the provisions of rule 703, relating to opinion testimony by expert witnesses.

Rule 702. Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Rule 703. Bases of Opinion Testimony by Experts

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Rule 704. Opinion on Ultimate Issue

(a) Except as provided in subdivision (b), testimony in the form of an opinion or inference otherwise admissible

is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.

(b) No expert witness testifying with respect to the mental state or condition of a defendant in a criminal case may state an opinion or inference as to whether the defendant did or did not have the mental state or condition constituting an element of the crime charged or of a defense thereto. Such ultimate issues are matters for the trier of fact alone.

Rule 705. Disclosure of Facts or Data Underlying Expert Opinion

The expert may testify in terms of opinion or inference and give reasons therefor without prior disclosure of the underlying facts or data, unless the court requires otherwise. The expert may in any event be required to disclose the underlying facts or data on cross-examination.

Rule 802. Hearsay Rule

Hearsay is not admissible except as provided by these rules or by other rules prescribed by the Supreme Court pursuant to statutory authority or by Act of Congress.

Rule 803. Hearsay Exceptions; Availability of Declarant Immaterial

The following are not excluded by the hearsay rule, even though the declarant is available as a witness:

. . .

(18) **Learned treatises.** To the extent called to the attention of an expert witness upon cross-examination or relied upon by the expert witness in direct examination, statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. If admitted, the statements may be read into evidence but may not be received as exhibits.

. . .

(24) **Other exceptions.** A statement not specifically covered by any of the foregoing exceptions but having equivalent circumstantial guarantees of trustworthiness, if the court determines that (A) the statement is offered as evidence of a material fact; (B) the statement is more probative on the point for which it is offered than any other evidence which the proponent can procure through reasonable efforts; and (C) the general purposes of these rules and the interests of justice will best be served by admission of the statement into evidence. However, a statement may not be admitted under this exception unless the proponent of it makes known to the adverse party sufficiently in advance of the trial or hearing to provide the adverse party with a fair opportunity to prepare to meet it, the proponent's intention to offer the statement and the particulars of it, including the name and address of the declarant.

Rule 804: Hearsay Exceptions; Declarant Unavailable

. . .

(b) **Hearsay exceptions.** The following are not excluded by the hearsay rule if the declarant is unavailable as a witness:

. . .

(5) **Other exceptions.** A statement not specifically covered by any of the foregoing exceptions but having equivalent circumstantial guarantees of trustworthiness, if the court determines that (A) the statement is offered as evidence of a material fact; (B) the statement is more probative on the point for which it is offered than any other evidence which the proponent can procure through reasonable efforts; and (C) the general purposes of these rules and the interests of justice will best be served by admission of the statement into evidence. However, a statement may not be admitted under this exception unless the proponent of it makes known to the adverse party sufficiently in advance of the trial or hearing to provide the adverse

party with a fair opportunity to prepare to meet it, the proponent's intention to offer the statement and the particulars of it, including the name and address of the declarant.

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IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1992

No. 92-102

WILLIAM DAUBERT, *et al.*,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

On Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit

BRIEF FOR THE AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE AND THE NATIONAL ACADEMY OF SCIENCES AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

INTEREST OF *AMICI CURIAE*[1/]

The American Association for the Advancement of Science ("AAAS") is a non-profit scientific society that, among other objectives, seeks to increase public understanding and appreciation of the importance and promise of science in advancing human progress. Founded in 1848, the AAAS is now the world's largest general scientific organization. It has nearly 300 affiliate organizations, and more than 134,000 scientists, engineers, educators, policy

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1/ This brief is filed with the permission of the parties. Written consents have been provided to the Clerk of this Court.

makers, and interested citizens among its members. *Science*, the official journal of the AAAS since the turn of the century, is one of the world's most frequently cited scientific journals.

The National Academy of Sciences ("NAS") is one of the world's most prestigious scientific organizations. It is a private, self-perpetuating organization, and selection for membership is a significant honor. Its congressional charter, which was signed into law by President Lincoln, provides that the Academy "shall, whenever called upon by any department of the Government, investigate, examine, experiment, and report upon any subject of science or art . . . ." 36 U.S.C. § 253 (1988). Working through the National Research Council, the Academy examines scientific and technological questions of national importance, typically referred to it by Congress or the Executive Branch.

Amici have had a continuing involvement in the intersection of science and law.[2/] *Amici* file this brief because of their interest in assuring that the courts avoid reliance on putatively scientific evidence that does not in fact reflect the application of scientific principles. Such evidence can lead to incorrect decisions and can serve to discredit the contributions of science. Scientists have an interest in

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[2/] The Academy, for example, recently issued a detailed report dicussing the possible forensic applications of DNA typing. *See* National Research Council, *DNA Technology in Forensic Science* (1992). This report devotes an entire chapter to issues concerning the admissibility of DNA evidence in criminal and civil proceedings.

assuring that the fruits of their labors are understood and properly used by others in society.

This case presents an important opportunity to clarify how courts should evaluate and screen scientific evidence. Petitioners assert that the authority of the federal courts to exclude such evidence should be narrowly constrained. *Amici* disagree. In evaluating scientific evidence, courts should consider the same factors that scientists themselves employ to assess the validity and reliability of scientific assertions.

Amici have filed this brief to explain those factors that are particularly relevant to the case pending before the Court and the way in which scientists apply them in the day-to-day practice of their profession. Although *amici* do not comment directly on the available evidence concerning the alleged teratogenicity of Bendectin, they support Respondent's position that courts have the authority and the responsibility to exclude expert testimony that is based upon unreliable or misapplied methodologies.

SUMMARY OF ARGUMENT

The courts below correctly recognized the difficulties that attend the consideration and use of scientific evidence in the courtroom. Such evidence often may be difficult to assess and yet may be of determinative significance. To avoid outcomes that are at odds with reality, courts must exercise special care to assure that such evidence is based on valid and reliable scientific methodologies.

Courts can best accomplish this difficult task by applying the same criteria that scientists themselves regularly apply in picking and choosing the theories, explanations, and methods upon which they build their own work. Although the details of science may be remote from common experience, judges can understand the fundamental characteristics that separate good science from bad. Courts should also consider the institutional mechanisms, namely the different forms of peer review, that have been developed to assure that scientists conduct their work in accordance with appropriate scientific criteria.

When faced with disputes about expert scientific testimony, judges should make full use of the scientific community's criteria and quality-control mechanisms. To be admissible, scientific evidence should conform to scientific standards and should be based on methods that are generally accepted by the scientific community as valid and reliable. Threshold determinations concerning the admissibility of scientific evidence are necessary to ensure accurate decisions and to avoid unnecessary expenditures of judicial resources on collateral issues. Judicial control of this sort is fully in keeping with the Federal Rules of Evidence.

ARGUMENT

I. SCIENTIFIC EXPERT TESTIMONY POSES SPECIAL CHALLENGES FOR COURTS AND NON-SCIENTIST FACT-FINDERS.

Scientific evidence can present special problems in litigation. It is often couched in peculiar terms, may derive from complicated scientific principles and seemingly unusual methods of proof, and sometimes addresses issues of fact that are very different from those confronted in everyday life.[3/] Because fact-finders may perceive expert scientific evidence as carrying a special stamp of certainty and authority, they sometimes give particular credence to scientific experts.[4/]

3/ *See* Loevinger, *Standards of Proof in Science and Law*, 32 JURIMETRICS J. 323, 333 (1992) ("[T]he basic techniques of science are measuring and counting, and the language that best expresses the data gathered by these techniques is the language of numbers. . . . [S]cientific standards of proof are expressed numerically, stating degrees of probability or confidence, while legal standards of proof are categorical and expressed entirely in verbal terms." (footnote omitted)); Elliott, *Toward Incentive Based Procedure: Three Approaches for Regulating Scientific Evidence*, 69 B.U.L. REV. 487, 487-88 n.3 (1989) ("By their very nature, disciplines such as toxicology rely on specialized techniques that run counter to a lay person's intuitions." (citation omitted)).

4/ *See* United States v. Brown, 557 F.2d 541, 556 (6th Cir. 1977) ("Because of its apparent objectivity, an opinion that claims a scientific basis is apt to carry undue weight with the trier of fact."); United States v. Addison, 498 F.2d 741, 744 (D.C. Cir. 1974) ("scientific proof may in some instances assume a posture of mystic infallibility in the eyes of a jury of laymen").

Scientific evidence may also have particular importance in certain types of litigation because it can illuminate crucial issues that otherwise would remain in darkness. For example, in a toxic tort case, science can provide unique insights into the likelihood that exposure to a certain chemical caused the injury at issue. Such testimony may provide the sole foundation for determining whether a plaintiff can satisfy a causation requirement.

Finally, scientific evidence presents unique challenges because it may not be able to provide definitive pronouncements. Scientists must often be satisfied with probabilistic statements made in the context of particular theoretical assumptions or experimental methodologies.[3/] The proper consideration of scientific evidence requires sensitivity to those assumptions and methodologies and to the reality that scientific knowledge is often evolving and changing.

The unique persuasive power of scientific evidence -- and its inherent limitations -- requires that courts engage in special efforts to ensure that scientific evidence is valid and reliable before it is admitted. In performing that task, courts can look to the same criteria that scientists themselves use to evaluate scientific claims.

3/ *See* Brennan, *Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substances Litigation*, 73 CORN. L. REV. 469, 478-83 (1988).

II. SCIENTISTS USE ESTABLISHED CRITERIA AND INSTITUTIONAL MECHANISMS TO EVALUATE SCIENTIFIC CLAIMS.

The scientific community has a special interest in encouraging innovative thinking while simultaneously ensuring that new ideas are subjected to rigorous review. On the one hand, science is a creative process in which advances occur only if researchers develop and test innovative ideas. Indeed, the scientific community reserves its highest honors for those individuals who have taken chances on novel approaches to problems. On the other hand, because science is a cumulative subject in which each scientist must build on the work of others, the scientific community also places great emphasis on weeding out false ideas. Accordingly, creativity is tempered by the need for rigorous testing and review of new approaches.

Individual scientists must be able to identify "good" science in pursuing their own research. The fundamental criteria they apply in doing so are neither arcane nor remote, and can be understood by educated and informed lay persons. Similarly, judges can understand and rely on the institutional processes that science has developed to help evaluate scientific assertions.

A. Science Represents An Ongoing Process Of Inquiry To Explain Natural Phenomena.

Science is not an encyclopedic body of knowledge about the universe. Instead, it represents a *process* for proposing and refining theoretical explanations about the world that are

subject to further testing and refinement.[6] Scientists accept a scientific explanation for an event when that explanation is corroborated by experiments using accepted methodologies and when it is consistent with other accepted explanations. Corroboration is generally based on the correct prediction of observed events or results. In some fields, such as cosmology, consistency with general theory may be especially important. In other fields, such as biochemistry, experimentation provides the primary means for evaluating hypotheses. In still other fields, such as astronomy, observation rather than experimentation is relied upon to corroborate theoretical predictions. At its core, however, science is a process of evaluating testable propositions to assure conformance with observable reality.

Although there is no simple recipe for the conduct of scientific work, science does proceed through a series of interrelated steps centered on the generation and testing of hypotheses. Hypotheses are educated guesses about a particular phenomenon or event. An hypothesis is tested for its internal consistency, explanatory value, and accuracy in predicting observed results.[7] Applying these basic requirements, one would reject an hypothesis which is self-contradictory, tautological, or inaccurate in predicting outcomes.

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[6] Loevinger, *supra* note 3, at 328 ("[S]cience is not so much a body of knowledge as an endless search for universal laws and a more inclusive coherent system of hypotheses.").

[7] *See* Ayala & Black, *The Nature of Science: A Primer for the Legal Consumer of Scientific Information*, 1 SCI. & COURTS 1 (Winter 1993).

Science thus involves far more than mere observation. Valid science must also explain and clarify relationships. The key to valid science is a convergence of well reasoned explanation with supporting observations or experimental results. No discrete set of experiments can establish that an hypothesis is true in all situations. Rather, scientists conduct rigorous experimental testing in an attempt to falsify hypotheses. An hypothesis is accepted as generally valid to the extent that it has survived repeated attempts at falsification. "*Observation*, *reason*, and *experiment* make up what we call the *scientific method*."[8]

In some instances, corroboration and consistency with existing theories may elevate an hypothesis to the status of a theory, which may eventually mature into a scientific law. For example, thermodynamics and Newton's laws of motion have achieved the status of laws, reflecting the high level of confidence that scientists place in the predictions that these laws provide.[9] It is only through a process of continual challenge that confidence in the validity of a scientific proposition may emerge.

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[8] R. FEYNMAN, R. LEIGHTON & M. SANDS, THE FEYNMAN LECTURES ON PHYSICS 2-1 (1963) (emphasis in original).

[9] Important observations can quickly become part of accepted scientific knowledge. The double-helix model of DNA first proposed by James Watson and Francis Crick in 1953 became accepted by the scientific community and was used as the basis for all research in molecular biology after the hypothesis was corroborated by critical experiments undertaken in 1958. Meselson & Stahl, *The Replication of DNA in* Escherichia coli, 44 PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES (U.S.A.) 671, 681-82 (1958).

B. In Pursuing Their Own Research, Scientists Routinely Evaluate The Work Of Colleagues.

In light of the immensity of contemporary scientific knowledge, no scientist could conceivably corroborate the validity of all of the theories, methods, and results on which he or she must rely in research. As a result, each scientist must decide whether to accept particular hypotheses or research data as the foundation for further work.[10/] This process involves the weighing of a variety of factors to ensure that the underlying work is reliable.

Scientists evaluate whether an hypothesis has been rigorously tested and whether the data have been derived using methods or protocols deemed acceptable in the field. In conducting such an evaluation, scientists consider the credentials of the proponent of a particular hypothesis or of the source of the data, including whether the research is in a field in which the proponent's education or experience indicates expertise. Reliance on an hypothesis generated by another might also depend on whether the experimental evidence is sufficient to reject reasonable alternative hypotheses and is consistent with existing scientific theories pertaining to that field. Similarly, reliance on another's research data might turn on an evaluation of the consistency of the results with data gathered by several others in the relevant field.

These considerations do not, of course, exhaust the range of criteria that scientists use in evaluating scientific

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10/ *See* Black, *A Unified Theory of Scientific Evidence*, 56 FORD. L. REV. 595, 620-26 (1988).

work, but they do reflect the basic concern for probing the foundations of research results to assess conformance with scientific standards. Scientists would, for instance, typically not be inclined to rely on an hypothesis based on nothing more than reinterpretations of existing data if the new hypothesis is uniformly inconsistent with the results of other previously published research. Because experimentation is itself subject to error, scientists also require replication of tests, particularly before rejecting important or previously corroborated hypotheses.

There is an obvious danger that research results generated solely for litigation may be skewed. "A scientist who has a formed opinion as to the answer he is going to find before he even begins his research may be less objective than he needs to be in order to produce reliable scientific results."[11/] Indeed, experts who testify about research results that have not been submitted for scientific scrutiny, despite ample opportunity for publication, may not be truly acting in their capacity as scientists. One court has observed that "many such able persons present studies and express opinions that they might not be willing to express in an article submitted to a refereed journal of their discipline or in other contexts subject to peer review."[12/]

11/ Perry v. United States, 755 F.2d 888, 892 (11th Cir. 1985); *see* Feinstein, *Scientific Standards in Epidemiological Studies of the Menace of Daily Life*, 242 SCIENCE 1257 (1988) (emphasizing importance of stipulating a research hypothesis in advance of data collection).

12/ *In re* Air Crash Disaster at New Orleans, 795 F.2d 1230, 1234 (5th Cir. 1986) ("That a person spends substantially all of his time (continued...)

Of course, not every scientific conclusion is of an importance that warrants publication or even detailed peer scrutiny. Some matters may have a significance in litigation that far exceeds their scientific interest. For example, the hydrological evaluation of a chemical waste site might have enormous import in litigation, but, unless some previously undetected phenomena were encountered, it would likely be of little general scientific interest. The test applied by scientists in evaluating such results would turn on whether their proponent has consistently adhered to the kind of reasoning that constitutes science, and has made plausible assumptions and used an accepted methodology in reaching his or her conclusions.[12]

On the other hand, research results that are advanced solely in litigation and that conflict with existing learning should be viewed with caution. Such information, if correct, is of scientific significance and ordinarily would warrant publication. Experts who propose to do nothing more with

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[12](...continued)
consulting with attorneys and testifying is not a disqualification. But experts whose opinions are available to the highest bidder have no place testifying in a court of law, before a jury, and with the imprimatur of the trial judge's decision that he is an 'expert.'"); *see also* Johnston v. United States, 597 F. Supp. 374, 414, 415 (D. Kan. 1984) ("[T]hese witnesses say and conclude things which, in the Court's view, they would not dare report in a peer-reviewed format."); Brent, *The Irresponsible Expert Witness: A Failure of Biomedical Graduate Education and Professional Accountability*, 70 PEDIATRICS 754, 755 (1982).

[13] *See* Kezsbom & Goldman, *The Boundaries of Groundwater Modeling Under the Law: Standards for Excluding Speculative Expert Testimony*, 27 TORT & INSUR. L.J. 109 (1991).

seemingly remarkable discoveries than submit them to judges and juries are not acting in a manner characteristic of scientists.[14] Presentation of the information to the scientific community in some fashion is the sole means by which the new work can become part of the body of scientific knowledge.

C. Institutional Checks Exist To Assist In Evaluating The Validity Of Scientific Research.

A new theory or explanation must generally survive a period of testing, review, and refinement before achieving scientific acceptance. This process does not merely reflect the scientific method; it is the scientific method.[15] Peer review, in its broadest sense, represents the scientific community's effort to police itself and to assure a certain minimum level of quality so that scientists and others can rely on the results of reported scientific research. Moreover,

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[14] *See Perry*, 755 F.2d at 892 ("[T]he examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or medicine."). The same complaint can be levied against scientists who attempt to avoid peer review by presenting their findings to the lay media, as happened a few years ago when Utah researchers announced at a press conference that they had discovered "cold fusion." The resulting controversy illustrates the importance of conducting confirmatory experiments and encouraging careful scrutiny by colleagues. *See Cold-Fusion Claim is Faulted On Ethics as Well as Science*, N.Y. Times, March 17, 1991, at 1; *Cold Fusion Still Escapes Usual Checks of Science*, N.Y. Times, Oct. 30, 1990, at C1, C8.

[15] *See* J. ZIMAN, RELIABLE KNOWLEDGE: AN EXPLORATION OF THE GROUNDS FOR BELIEF IN SCIENCE 130-32 (1978); Relman & Angell, *How Good is Peer Review?*, 321 NEW ENGL. J. MED. 827, 828 (1989).

peer review contributes to the advancement of science not merely through the screening of scientific work, but also by helping proponents of new hypotheses to improve their research and interpretations.

This scientific scrutiny takes place in a variety of contexts. As one court has explained:

> Scientific truth and the acceptability of scientific procedure are not normally established by public opinion polls. The scientific community uses entirely different methods for such purposes (*e.g.*, articles in learned journals, seminars, acceptance at institutions of higher learning). . . . [These procedures] are time-honored precisely because scientific truth generally requires this kind of maturation of a consensus.[16]

Informal peer review can occur when scientists discuss their work with one another at the laboratory bench, during conversations and seminars, and at scientific meetings. Formal peer review is generally an intrinsic part of the scientific publication process and the process by which funds are allocated for the conduct of research. At a minimum, any claim that would significantly add to or change the body of scientific knowledge is regarded skeptically until it has been subject to some form of peer scrutiny.

Peer review of manuscripts submitted to scientific journals is a fundamental part of scientific practice.

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[16] Dowd v. Calabrese, 585 F. Supp. 430, 432 (D.D.C. 1984).

Typically, the editors of a journal call on the assistance of outside experts to "referee" manuscripts -- that is, to provide advice on their suitability for publication.[17] Referees enlisted to peer review manuscripts do not merely provide recommendations as to whether a study should be published. Instead, their primary job is to provide constructive criticism so that a manuscript or the underlying research can be improved.

Because scientific work often depends upon complex underlying assumptions and choices of methodology, probing and careful review by other scientists is indispensable. Dr. William W. Havens, Jr., Professor Emeritus of Applied Physics at Columbia University, has explained that "[s]cience is a cumulative enterprise in which each scientist builds on the work of others. Because of the enormous expense that would be associated with reproducing the results of others, a scientist must rely to a significant extent on the validity of reported results."[18] Publication in peer-reviewed journals

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[17] *See* Solarex Corp. v. Arco Solar, Inc., 121 F.R.D. 163, 164, 167-68 (E.D.N.Y. 1988) (use of qualified editors and outside referees provides an important quality-control mechanism for scientific publications), *aff'd*, 870 F.2d 642 (Fed. Cir. 1989); Lock & Smith, *What Do Peer Reviewers Do?*, 263 J.A.M.A. 1341 (1990).

[18] Affidavit quoted in *Solarex*, 121 F.R.D. at 171. As a result, "the peer review function performed by independent referees for editors of scholarly journals contributes to the advancement of science by helping to assure that 'faulty, incomplete or misleading results are not published.'" *Solarex*, 121 F.R.D. at 171; *see also Policy of AMA Journals Regarding Release of Information to the Public*, 265 J.A.M.A. 400 (1991) ("All concerned want medical information to be as accurate as

(continued...)

is one of the most important mechanisms for screening, disseminating, and preserving new research results. Publication also engages scientists in a public dialogue about new research, providing an opportunity for clarification and refinement.

The use of peer review in the publication process has its critics, and their complaints must be given due consideration.[19] For example, some have argued that peer review stifles innovation,[20] and even its defenders concede that the process cannot always ferret out scientific fraud,[21] or provide a guarantee of scientific validity.[22] Even the most

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[18](...continued)
possible. Medical editors rely on rigorous peer review to evaluate such accuracy prior to accepting papers . . . .").

[19] The editors of the *Journal of the American Medical Association* devoted an entire issue to articles addressing problems surrounding peer review in the publication process. *Guarding the Guardians: Research on Editorial Peer Review*, 263 J.A.M.A. 1306-1456 (March 9, 1990).

[20] *See* Horrobin, *The Philosophical Basis of Peer Review and the Suppression of Innovation*, 263 J.A.M.A. 1438 (1990).

[21] *See* Rennie, *Editors and Authors*, 261 J.A.M.A. 2543, 2544 (1989) ("[A]lthough it may work well when the questions being asked of it are the questions of science, peer review has proved to be of little use in determining if the information provided in the first place is either complete or honest."); *Bill Would Set Fraud Guidelines for Scientific Publications*, 242 SCIENCE 187 (1988).

[22] *See* Relman & Angell, *supra* note 15, at 828 ("[A]lthough peer review can screen out work that is clearly invalid and greatly improve the chances that published work is valid, it cannot guarantee scientific validity.").

vocal critics of the peer review system do not, however, recommend that it be dismantled.[23] Indeed, in response to some of these complaints, scientific organizations have made efforts to improve the integrity of the process. Although by no means perfect, peer review in the publication process is relied upon by the scientific community as the best means for identifying valid scientific research and conclusions.[24]

Federal agencies often rely on peer-review processes to allocate scarce federal research dollars to those projects that hold the greatest scientific promise.[25] Federal regulatory agencies have also placed increasing reliance on the expertise of outside scientists through the establishment of special advisory committees or some other form of peer review. The Food and Drug Administration ("FDA") and the Environmental Protection Agency ("EPA") have been at the forefront of this trend. Some of these expert advisory

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[23] *See* Horrobin, *supra* note 20; Knoll, *The Communities of Scientists and Journal Peer Review*, 263 J.A.M.A. 1330 (1990).

[24] *See* Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of* Agent Orange *and Bendectin Litigation*, 86 NW. U. L. REV. 643, 694-95 n.210 (1992) (discussing flaws identified with peer review system, but concluding that courts do not have any more refined mechanism for determining the validity of scientific studies); Klein, *Expert Testimony in Pharmaceutical Product Liability Actions*, 45 FOOD DRUG COSM. L.J. 393, 427 (1990).

[25] *See, e.g.*, 42 U.S.C. § 289a (1988) (requiring peer review of NIH grant applications); 42 C.F.R. § 52h.7(a) (1991) (NIH regulations); 45 C.F.R. Pt. 602 (1991) (National Science Foundation regulations).

committees have been established by statute,[26/] while a great many others are agency creations.[27/] Indeed, in some instances, Congress has mandated the use of peer review for certain agency actions.[28/]

In sum, peer review provides courts with many sources of information that may be useful in evaluating scientific evidence. Courts should make full use of the considered opinions of the scientific community when attempting to assess such evidence.

[26/] *See, e.g.*, 7 U.S.C. § 136w(d) (1988) (EPA's Scientific Advisory Panel, which is concerned with pesticide registrations); 21 U.S.C. § 360c(b) (1988 & 1992 Supp.) (FDA's medical device classification panels); 21 U.S.C. § 376(b)(5) (1988) (FDA's color additive advisory committees).

[27/] *See, e.g.*, 21 C.F.R. § 14.100 (1992) (listing FDA's numerous standing advisory committees). The Administrative Conference has endorsed the use of such advisory committees because "[t]he quality and legitimacy of . . . agency decisions can be improved by counseling with eminent scientific experts outside the agency." 1 C.F.R. § 310.11 (1992). Courts reviewing agency actions based on complicated scientific evidence have echoed this sentiment. *See* Asbestos Information Ass'n v. Occupational Health & Safety Admin., 727 F.2d 415, 421 & n.15 (5th Cir. 1984).

[28/] *See, e.g.*, 7 U.S.C. § 136w(e) (1988) (requiring peer review of major scientific studies concerning pesticides conducted by or with the EPA); 42 U.S.C. § 9604(i)(13) (1988) (Superfund provision requiring that "[a]ll studies and results of research conducted under this subsection (other than health assessments) shall be reported or adopted only after appropriate peer review"); 42 U.S.C. § 1396r-8(k)(6) (1992 Supp.) (authorizing Medicaid reimbursement for any use of a prescription drug that "appears in peer-reviewed medical literature" even if FDA has not specifically approved that use of the drug).

III. COURTS SHOULD EXCLUDE EXPERT TESTIMONY DERIVED FROM THEORIES, REASONING, OR METHODOLOGIES THAT DO NOT CONFORM TO SCIENTIFIC CRITERIA AND STANDARDS.

Courts should admit scientific evidence only if it reasonably conforms to scientific standards and is derived from methods that are generally accepted as valid and reliable. Such a test for admissibility would incorporate the factors, including the results of peer review, that scientists consider in evaluating each other's work.

A. In Evaluating Disputed Scientific Evidence Courts Should Consider The Same Factors That Scientists Consider.

Although many judges may lack extensive scientific training, they can understand the basic characteristics that separate valid science from mere speculation. The scientific commitment to providing explanations that are supported by observational and experimental evidence should apply when an expert testifies in court, just as it does when he or she reports results to other scientists. Only in this way can prejudicial speculation be distinguished from valid science. Indeed, the basic logic of science does not differ from the logic of the law. In both, understandable explanations must connect evidence to conclusions about the evidence.[29/]

Courts can and should decide disputes about scientific evidence based on an understanding of the overarching

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[29/] *See* Loevinger, *supra* note 3, at 328 & n.26.

principles that govern the way good science is conducted. For example, a physician should not be allowed to claim that a substance caused someone to develop a common illness simply because another of his patients developed a similar illness after years of exposure to the same substance. Similarly, an expert should not be permitted to assert that a substance is a human carcinogen on the basis of nothing more than inconclusive animal testing. Although these observations may provide an interesting foundation from which to generate hypotheses about causation that warrant careful exploration, no scientist would accept the offered conclusions, without more, as scientifically valid. Courts likewise should have no trouble in recognizing the shortcomings of such evidence if they assess these assertions against the basic criteria of scientific validity.

The characteristics of valid science are neither remote nor arcane, and a judge should not hesitate to consider them in evaluating disputed scientific evidence. Although judges often will be unable to bring the same expertise to such a task as a specially trained scientist, they are in a position to determine if scientific evidence possesses the characteristics of valid science and to consider the same factors that busy scientists use to evaluate research performed by other scientists. To the extent that a judge feels a need for additional information or guidance in making determinations of scientific validity, Rule 706 of the Federal Rules of Evidence authorizes the appointment by the court of experts to assist in such matters.

B. Courts Should Take Into Account The Results Of Peer Review In Assessing The Validity And Reliability Of Scientific Evidence.

In evaluating the admissibility of scientific evidence, courts should consider not only the characteristics of valid science, but also the extent to which a claim has been subjected to peer review by other scientists. *Amici* do not assert that peer review or publication is either a necessary or a sufficient condition for establishing the validity of a scientific claim. Some published research later may prove to be invalid, and research that has been rejected for publication may, in some situations, turn out to be perfectly valid. For purposes of guiding courts, however, survival of peer-review scrutiny provides a useful indicator of the judgments of other scientists about the validity of new hypotheses. Unreviewed research has not yet survived the screening function that scientists customarily demand in the dissemination of scientific results.

The need for skepticism of unreviewed research is especially important when an expert expresses disagreement with a substantial body of published research, offering instead his or her own unpublished conclusions. No court should permit an expert to testify in a paternity suit that he believes, on the basis of unreported experiments demonstrating the importance of environmental influences, that the theory of heredity offers no guidance for establishing the identity of a child's father. Nor should a judge countenance the introduction of testimony in a traffic-accident case that disputes the application of Newton's laws of motion, no matter how sincere the expert's claim. Although these

situations represent extreme cases, it is clear that a court must have the power to reject such testimony. Even if these experts have stumbled onto something truly remarkable, such breakthroughs should not be resolved by a court of law in the first instance.

C. Courts Should Determine The Competence Of Scientific Evidence As A Threshold Matter.

Determinations concerning the admissibility of expert testimony based on scientific evidence should be made by a judge in advance of trial. Such judicial control is explicitly called for under Rule 104(a) of the Federal Rules of Evidence,[20] and threshold admissibility determinations by a judge serve several important functions, including simplification of issues at trial (thereby increasing the speed of trial), improvement in the consistency and predictability of results, and clarification of the issues for purposes of appeal. Indeed, it is precisely because a judge can evaluate the evidence in a focused and careful manner, free from the prejudices that might infect deliberations by a jury, that the determination should be made as a threshold matter.[21]

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[20] *See* United States v. Haro-Espinosa, 619 F.2d 789, 795 (9th Cir. 1979) (expert qualifications are preliminary question for the judge).

[21] *See In re* Agent Orange Product Liab. Litig., 611 F. Supp. 1267, 1269 (E.D.N.Y. 1985) ("The uncertainty of the evidence in [toxic tort] cases, dependent as it is on speculative scientific hypotheses and epidemiological studies, creates a special need for robust screening of experts and gatekeeping under Rules 403 and 703 by the court."), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988).

In rare cases, it may be difficult to distinguish truly revolutionary advances in science from aberrant hypotheses that will never be corroborated.[22] The best decision rule in such a situation may be to err on the side of caution and exclude the evidence. Although a favorable decision for a party who relies on dubious science does not result in an imprimatur of validity within the scientific community,[23] it can unwittingly inject bad science into broader decisions affecting society (for example, by encouraging meritless litigation against the producers of products that in fact are safe, or, even worse, by causing the abandonment of products that might prevent injuries). Subjecting uncorroborated hypotheses to heightened skepticism pending further testing and review is, thus, consistent with the aims of the law as well as those of science.

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[22] It is unlikely that a court will be faced with an expert proposing a true breakthrough and, in any event, "it is extremely unlikely that there will be any judges scientifically sophisticated enough to recognize such a genius, or his theories, before the scientific community gives its recognition." Loevinger, *Science and the Legal Rules of Evidence--A Review of Galileo's Revenge*, 32 JURIMETRICS J. 487, 495 (1992).

[23] *See, e.g.*, Wells v. Ortho Pharmaceutical Corp., 788 F.2d 741, 744-45 (11th Cir.) (upholding verdict in favor of person who claimed that her birth defects had been caused by a spermicidal jelly used by her mother), *cert. denied*, 479 U.S. 950 (1986). Two physicians from the National Institute of Child Health and Human Development noted that the "decision took the medical community by surprise, because the overwhelming body of evidence indicates that spermicides are not teratogenic." Mills & Alexander, *Teratogens and Litogens*, 315 NEW ENGL. J. MED. 1234, 1235 (1986).

D. Threshold Determinations Concerning The Admissibility Of Scientific Evidence Are Consistent With The Federal Rules Of Evidence.

The approach to scientific expert testimony suggested by *amici* fits within the plain meaning of the Federal Rules of Evidence. Three rules determine what a court must consider in determining whether to admit such testimony:

> (1) Rule 702 sets forth the kinds of knowledge about which experts can testify, who qualifies as an expert, and how the testimony must relate to the facts of the case.
>
> (2) Rule 703 requires that the facts or data upon which an expert bases his or her opinions or inferences must be of a type reasonably relied upon for that purpose in the expert's field.
>
> (3) Rule 403, which applies to all evidence, allows a court to exclude otherwise admissible scientific evidence if its probative value is substantially outweighed by the danger of unfair prejudice or other countervailing factors.

Taken together, these rules provide judges with ample authority to screen and exclude expert testimony based on dubious science.

Under Rule 702, a party seeking to introduce scientific knowledge through a qualified expert must establish that the evidence is based on scientific principles. In applying this standard, the court must focus its inquiry on the putative

expert's reasoning.[24] Properly applied, Rule 702 authorizes scientifically qualified witnesses to testify, but their testimony must be founded on scientifically valid methodologies.

Rule 703 allows experts to base opinions or inferences on facts or data not admissible as evidence, but only if the facts or data are of a type reasonably relied upon within the expert's field. The plain language of the Rule makes clear that scientific standards apply to the factual basis for expert testimony, and that an expert's reliance on facts must be in accord with the practices of the field. Although it is more limited in scope than Rule 702, Rule 703 reflects the overall concern that scientific experts adhere to scientific standards when they testify.[25]

Rule 403 also emphasizes the need to scrutinize scientific evidence closely. The Rule provides that relevant

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[24] *See* Christophersen v. Allied Signal Corp., 939 F.2d 1106, 1115 (5th Cir. 1991) (per curiam) (expert must connect the facts to conclusion in a scientifically valid way), *cert. denied*, 112 S. Ct. 1280 (1992); Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 310 (5th Cir. 1989) ("courts must critically evaluate the reasoning process by which the experts connect data to their conclusions"), *cert. denied*, 494 U.S. 1046 (1990); Hull v. Merck & Co., 758 F.2d 1474, 1477 (11th Cir. 1985). *See also* Black, *supra* note 10.

[25] *See* Brown v. Parker-Hannifin Corp., 919 F.2d 308, 311 (5th Cir. 1990); Slaughter v. Southern Talc Co., 919 F.2d 304, 306-07 (5th Cir. 1990) (court should assess the reliability of the sources of an expert opinion); Head v. Lithonia Corp., 881 F.2d 941, 944 (10th Cir. 1989) (court must make preliminary determination whether the data underlying an expert's conclusion is reasonably relied upon by experts in the field).

and otherwise admissible evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.[26] For scientific evidence, the evaluation of probativeness necessarily involves the same kind of validity and reliability analysis that is required under Rules 702 and 703.[27] Consideration of the other factors enumerated in Rule 403 reinforces the basic theme: requiring the jury to listen to a battle of experts over the merits of an unreliable scientific procedure or theory can only create confusion by focusing the jury on a collateral issue at the expense of valuable time. If arguably invalid scientific evidence were to be admitted as a matter of course, the party opposing it would have to be allowed time to educate the jury about science and the deficiencies of the particular evidence in question, which is exactly the kind of misallocation of judicial resources that Rule 403 seeks to prevent.[28]

Close judicial scrutiny of the foundations for expert testimony is commended by the Federal Rules of Evidence,

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[26] *See* Turner v. Allstate Insur. Co., 902 F.2d 1208, 1214 (6th Cir. 1990) (upholding exclusion of survey because "the statistical data had a serious potential for confusing the jury and being misinterpreted").

[27] *See* Viterbo v. Dow Chemical Co., 826 F.2d 420, 422-24 (5th Cir. 1987) (upholding exclusion of expert testimony which lacked any reliable scientific foundation).

[28] *See In re* Agent Orange Product Liab. Litig., 611 F. Supp. 1223, 1256 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988).

which direct courts to control the admission of evidence to facilitate accurate fact-finding. To best accomplish this objective when addressing the admissibility of scientific evidence, courts should make full use of the scientific community's own standards and techniques for judging the validity and reliability of new hypotheses and research.

* * * *

The scientific community's well established criteria and institutional mechanisms for evaluating the validity of scientific assertions provide courts with clear and understandable guidance on how they can rationally and consistently evaluate scientific evidence. Courts should admit scientific evidence only if it conforms to scientific standards and is derived from methods that are generally accepted by the scientific community as valid and reliable. Such a test promotes sound judicial decisionmaking by providing workable means for screening and assessing the quality of scientific expert testimony in advance of trial.

CONCLUSION

For the foregoing reasons, *amici* urge this Court to uphold the broad authority of courts to exclude putatively scientific evidence that does not, according to the standards applied by the scientific community, have the earmarks of scientific reliability.

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IN THE
SUPREME COURT OF THE UNITED STATES
October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT,
Individually and As Guardians Ad Litem for
JASON DAUBERT, and ANITA DE YOUNG, Individually
and As Guardian Ad Litem for ERIC SCHULLER,
Petitioners,

vs.

MERRELL DOW PHARMACEUTICALS, INC.
Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF AMICUS CURIAE THE DEFENSE RESEARCH INSTITUTE, INC. IN SUPPORT OF RESPONDENT

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IDENTITY AND INTEREST OF AMICUS CURIAE

The Defense Research Institute, Inc. (hereinafter "DRI") is a national, not-for-profit, incorporated association whose purpose is to enhance the services of the legal profession to the public, to improve the adversary system, and to work for the prompt, fair disposition of claims. DRI has a membership in excess of 18,000 trial attorneys and over 400 insurers and other corporations. DRI files an amicus brief because of the substantial public interest in matters involved in this case. The issues presented for consideration are critical in terms of their implications for the adversarial process and the fair, predictable administration of justice.

DRI's interest in this matter is twofold. First, as a trial attorneys' organization, DRI is vitally concerned with the ultimate impact this Court's ruling will have on its members. Second, and more importantly, DRI is concerned with the effect this case will have on the judicial system in the trials of civil and criminal lawsuits. Moreover, the ruling by this Court may well have a dramatic impact upon the standards of conduct with which each citizen of the United States and each member of DRI must comply.

DRI has a national, state and community-wide reputation for thorough and objective research and evaluation of legal matters. As its name implies, it functions to provide complete research and research facilities to its members. DRI files as amicus in order to provide this Court with its research and well-reasoned brief. Because of its unique position, DRI speaks for a large group of trial attorneys who are concerned with the impact of the opinion to be rendered by this Court. This Court will be aided, not only by DRI's research in this area, but also by DRI's discussion of views on the issues which this case presents.

SUMMARY OF ARGUMENT

Rules of evidence, like any other rule of law, should serve the broad societal interests of evenhanded, consistent, and predictable application of legal rules, founded upon bedrock principles rather than in the proclivities of individuals. A rule of evidence which permits expert opinions based upon tenets or techniques not generally accepted by the scientific or medical community creates unpredictability of the duties owed by one citizen to another and establishes standards of care based upon individual proclivities, rather than societal norms. Interpreting the Federal Rules of Evidence so as to require general acceptance within the scientific or medical community as a foundational prerequisite to the admissibility of expert opinions would ensure fairness, predictability, and a uniform guide against which citizens of the United States can measure their conduct. Such a standard would not discourage scientific or medical development, while adoption of a rule of evidence which has as its sole foundational prerequisite "a willingness to testify" would dramatically reduce scientific and medical development to the grave detriment of the public. The general acceptance standard would have no greater effect on the outcome of diversity cases than does any other Federal Rule of Evidence and would not significantly change the outcome of cases tried in the federal courts, as contrasted to those tried in the state courts, since the overwhelming majority of the states follow the general acceptance standard or require reasonable reliability as a foundational prerequisite to the admissibility of scientific or medical testimony.

ARGUMENT

I. FAIRNESS, PREDICTABILITY, AND FEDERAL RULE OF EVIDENCE 102 REQUIRE GENERAL ACCEPTANCE BY THE SCIENTIFIC OR MEDICAL COMMUNITY AS A FOUNDATIONAL PREREQUISITE TO THE ADMISSIBILITY OF EXPERT TESTIMONY.

A. Rules of Evidence Which Permit Expert Opinions Based Upon Tenets Or Techniques Not Generally Accepted By The Scientific Or Medical Community Create Unpredictability And Establish Standards Of Care Based Upon Individual Proclivities Rather Than Societal Norms.

Federal Rule of Evidence 102 clearly states one of the primary purposes of rules of law:

> These rules shall be construed to secure fairness ... and promotion of growth and development of the law of evidence to the end that the truth may be ascertained and proceedings justly determined.

It cannot be gainsaid that any rule of law, whether substantive or a rule of evidence, in order to promote fairness, must also promote predictability. As stated in Vasquez v. Hillery, 474 US 254, 265 (1986):

> Today's decision is supported, though not compelled, by the important doctrine of stare decisis, the means by which we ensure that the law will not merely change erratically, but will develop in a principled and intelligible fashion. That doctrine permits society

> to presume that bedrock principles are founded in the law rather than in the proclivities of individuals, and thereby contributes to the integrity of our constitutional system of government, both in appearance and in fact. [emphasis supplied]

This Court, again in the context of the doctrine of stare decisis, has clearly articulated predictability as a cornerstone of the law:

> The doctrine of stare decisis imposes a severe burden on the litigant who asks us to disavow one of our precedents. For that doctrine not only plays an important role in orderly adjudication; it also serves the broader societal interests in evenhanded, consistent and predictable application of legal rules.

Thomas v. Washington Gas Light Co., 448 US 261, 272 (1980) (emphasis supplied).

This Court, in determining the weighty issue before it, must address a simple question -- does the interpretation of the Federal Rules of Evidence advanced by Petitioners promote fairness, predictability and evenhanded justice? In answering that question, the Court need not debate whether Frye v. United States, 293 F. 1013 (D.C. Cir. 1923) "survived" adoption of the Federal Rules of Evidence. Federal Rule of Evidence 102 requires construction of the rules so as to secure fairness and justice. Federal Rule of Evidence 702 permits expert testimony concerning "scientific, technical, or other specialized knowledge." Federal Rule of Evidence 703 requires the facts or data upon which an expert bases an opinion or inference be of the type "reasonably relied upon" by experts in the particular field in forming such opinions or inferences. The Federal Rules of

Evidence provide the line of demarcation: subject to the requirement that all rules of law be fair and promote predictability and evenhanded administration of justice, how should the phrases "scientific knowledge" and "reasonably relied upon by experts" be interpreted?

In determining the parameters of the Federal Rules of Evidence and the meaning to be given the phrases "scientific knowledge" and "reasonable reliability", the court must also bear in mind that resolution of such questions is not a purely philosophical pursuit. Rules of evidence have an ultimate, direct impact upon those citizens who appear before the Federal Courts -- based upon those rules, individuals lose their liberty, go free, are permitted or denied monetary recovery, or are compelled to pay vast sums of money. Thus, in a very real sense, the fundamental question before this Court will resolve a significantly broader question: to what societal norms must the citizens of the United States conform their conduct?

Against this backdrop, the Court must consider that interpretation of the Federal Rules of Evidence advanced by Petitioners. Petitioners reject an interpretation of the Rules which would require even the slightest degree of acceptance by the scientific or medical community, relying upon the language from United States v. Downing, 753 F.2d 1224, 1237 (3d Cir. 1985) which states:

> [G]eneral acceptance in the particular field ... should be rejected as an independent controlling standard of admissibility. Accordingly, we hold that a particular degree of acceptance of a scientific technique within the scientific community is neither a necessary nor a sufficient condition for admissibility.... [at 1237]

In turn, however, Petitioners also reject that portion of Downing

which requires the Court to independently determine basic reliability of the methodology of the expert witness. Essentially, Petitioners advance a single test for the admissibility of expert opinions -- is the expert qualified to offer the opinion? If so, all else goes to weight, not admissibility. In reality, Petitioners advance an interpretation suggested, but later rejected, by the United States Court of Appeals for the District of Columbia in Ferebee v. Chevron Chemical Co., 736 F.2d 1529 (D.C. Cir. 1984), where the Court stated:

> Judges, both trial and appellate, have no special competence to resolve the complex and refractory causal issues raised by the attempt to link low level exposure to toxic chemicals with human disease. On questions such as these, which stand at the front of current medical and epidemiological inquiry, if experts are willing to testify that such a link exists, it is for the jury to decide whether to credit such testimony. [emphasis supplied, at 1534]

Does such an interpretation of the Federal Rules of Evidence, when applied to the facts of either civil or criminal trials, serve the broader societal interests of evenhanded, consistent and predictable application of legal rules and ensure those rules are founded in bedrock principles rather than the proclivities of individuals? No. Rather, such a rule is based solely upon individual proclivities since, in the words of Ferebee v. Chevron Chemical Co., supra, the test for admissibility is whether the proffered expert is "willing to testify" to a given proposition, although the proposition has been rejected by the scientific community or is unproven by acceptable scientific methodology.

Such a rule of evidence, in application and in reality, has

consequence. The citizens of the United States would be left with virtually no guidelines to which they could conform their conduct. Physicians, hospitals, nurses, individual citizens and manufacturers of drugs, devices, consumer goods, or industrial products would have no guidance concerning the standards of conduct with which they must comply. Although they might comply with every known federal or state legislative or judicial requirement and although they might comply with the generally accepted body of science and medicine, they could, nevertheless, be found liable because one individual in the scientific or medical community was "willing to testify" to a given methodology or proposition, although such methodology or proposition had been uniformly rejected by the scientific community or had not gained acceptance as being reliable by the scientific or medical community because it had not yet been proven by verifiable scientific data. Thus, in a very real fashion, a rule of evidence which provides that a "particular degree of acceptance of a scientific technique within the scientific community is neither a necessary nor a sufficient condition for admissibility" creates a literal standard of care -- that standard to which a given individual is "willing to testify". Whether the testimony be offered in the utmost of good faith, scientific spirit or because substantial sums of money were paid for the particular opinion, it is beyond dispute that there is no predictability in the law when a rule of evidence will compel one to pay vast sums of money or cause one to be incarcerated because one person is "willing to testify" to a methodology or proposition. Such was the standard applied to the "witches" of Salem. Paraphrasing the words of this Court, the conduct of society would be governed by the proclivities of individuals, rather than bedrock principles and established societal norms.

B. Requiring General Acceptance Within The Scientific Community As A Foundational Prerequisite To Admissibility Is Consistent With Federal Rule Of Evidence 102 And Insures Fairness, Predictability, And A Uniform Guide Against Which Citizens Of The United States Can Measure Their Conduct

Having addressed the question of whether the interpretation advanced by Petitioners would promote fairness, uniformity and predictability, the Court should address whether the "general acceptance test" is consistent with the Federal Rules of Evidence and whether such a standard would promote fairness, predictability, and enhance the societal interest of evenhanded, consistent and predictable application of legal rules.

Federal Rule of Evidence 702 permits testimony by experts as to "scientific, technical or specialized knowledge", with Rule 703 further requiring the facts or data upon which an expert bases an opinion or inference be of a type "reasonably relied upon by experts in the particular field." In determining the meaning of those phrases, the Court must bear in mind the mandate of Rule 102, requiring construction of the rules to secure fairness and ensure justice.

Requiring general acceptance by the scientific or medical community of the methodology employed and, in some instances, of the conclusion reached, is entirely consistent with the language of the rules. "Scientific knowledge" and "reasonable reliability" should, in order to secure fairness and justice, be interpreted so as to require general acceptance. The reason for such a suggestion is simple: the sole interpretation of the Federal Rules of Evidence which will serve the societal interests of evenhanded, consistent and predictable application of legal rules, founded upon bedrock principles rather than the proclivities of individuals, is the

"general acceptance" rule. In determining a course of conduct governed by scientific or medical principles, the citizens of the United States will have a clear guide -- that which is generally accepted by the scientific or medical community. In the context of the case before this Court, the manufacturers of Bendectin, in the formulation and manufacture of Bendectin, will have an identification of that standard against which their conduct will be measured -- that generally accepted within the scientific and medical community, rather than that to which someone might be willing to testify 20 years later.

One might suggest that it is a difficult task for trial and appellate judges to determine that which is generally accepted within the scientific or medical community. Indeed, such a suggestion was made in Ferebee v. Chevron Chemical Co., supra, where the Court noted "Judges, both trial and appellate, have no special competence to resolve the complex and refractory causal issues raised [in the case]." With utmost deference, the rejoinder is simple: complexity of the judicial task does not permit abdication of the judicial function. Moreover, as amply demonstrated by the record below, litigants unquestionably possess the sophistication and skill to clearly educate trial and appellate courts as to that which has gained general acceptance or general rejection in the scientific or medical communities.

It should also be noted that utilization of a general acceptance standard as a foundational prerequisite to admissibility of expert testimony will not silence those who would offer "different" opinions. Rather, it will simply require those who have "different" opinions to follow generally accepted scientific or medical methodology in reaching conclusions and will prohibit testimony from those who are "willing to testify" to propositions which have been generally rejected by the scientific or medical community or which are not scientifically

proven or provable. On the one hand, those who follow verifiable scientific methodology would be permitted to offer opinions which do not fly in the face of science. On the other hand, testimony would be prohibited from those who fail to adhere to acceptable scientific protocols. Thus, for example, those who interpret data based upon verifiable, reliable scientific methodology could offer opinions regarding cause and effect. However, citizens would not be subjected to incarceration based upon the evil of testimony that one was not telling the truth because of the results of a lie detector test, since science and medicine have found the polygraph unreliable. Similarly, product manufacturers could not be held liable based upon testimony from an expert witness who followed "generally accepted methodology" in reaching the conclusion that gravity causes objects to fall up, not down, a conclusion both rejected by the scientific community and unprovable and unproven by science.

C. The General Acceptance Standard Would Not Discourage Scientific Or Medical Development, While Adoption Of The Approach Suggested By Petitioners Would So Discourage

Some would suggest utilization of the general acceptance standard would discourage scientific or medical development. The response is simple -- courtrooms are not laboratories. While it is true that utilization of the general acceptance standard would prohibit the imposition of civil or criminal liability in the absence of application of generally accepted scientific or medical methodology or in those circumstances where science or medicine had rejected conclusions to which "one was willing to testify", it is equally untrue that such a rule of evidence would discourage scientific or medical development or research. Those who seek the cure for cancer or, indeed, those who seek to establish a cause

and effect relationship between Bendectin and birth defects, will continue to have the same encouragement which presumably induced their endeavor -- promotion of public health, welfare and safety. The Galileos, Newtons and Einsteins should and will continue their endeavors, doing so in the atmosphere of the laboratory, not the courtroom. However, until their work has risen to the level of a reasonable, predictable societal norm -- general acceptance within the scientific or medical community -- those who have relied upon and measured up to those reasonable, predictable societal norms will not be held civilly or criminally responsible for adhering to generally accepted bedrock principles rather than the proclivities of individuals which might or might not be found to be scientifically or medically accurate in the future. In short, those imprisoned because of polygraph results would have never lost their liberty.

On the other hand, science and medicine will, in great probability, be impeded if the legal standard for the admissibility of expert testimony is such that a particular degree of acceptance of scientific technique within the scientific community is neither a necessary nor sufficient condition for admissibility. If the individual and corporate citizens of the United States who manufacture goods and provide services face the potential of civil liability or criminal incarceration because "one is willing to testify", it is irrefutable that such individuals and corporations are positively discouraged from their scientific and medical endeavors. Suggestions that potential civil liability and potential payment of millions of dollars based upon "novel" science is a voluntary undertaking and a cost of doing business ignores reality and, more fundamentally, ignores a cornerstone of the law -- societal norms, not individual whims, define societal responsibility. Suggesting that the general acceptance standard should be rejected because one may be denied recovery based

upon science that may later be proven true also ignores another fundamental proposition of law -- society does not find one culpable because something is possibly true (see, e.g., opinion of District Court below, Petition For Writ of Certiorari, at page A-15). Our society has long recognized that imposition of civil liability or restriction of individual liberty must be necessarily based upon provable probability.

II. THE COURT SHOULD NOT REJECT THE GENERAL ACCEPTANCE STANDARD BECAUSE OF ITS POTENTIAL EFFECT ON THE OUTCOME OF DIVERSITY CASES

A. Most, If Not All, Of The Federal Rules Of Evidence Potentially Effect The Outcome Of Diversity Cases

Both Petitioners and Amici in support of Petitioners have suggested this Court should reject the general acceptance standard because it has the potential effect of determining the outcome of cases based upon diversity of citizenship. If this Court is prohibited from interpreting its own rules of evidence because interpretation of the rules might effect the outcome of diversity cases, this Court has no choice but to cause the repeal of all Federal Rules of Evidence. Most, if not each, of the Federal Rules of Evidence potentially effect the outcome of diversity cases. Simplistically, the rules of evidence effect the admissibility of evidence. The admissibility of evidence necessarily effects the outcome of cases. Every state in the Union has rules relating to the admissibility of hearsay evidence. Nevertheless, this Court has adopted Federal Rules of Evidence 802 through 805 relating to hearsay evidence. Many states would prohibit admissibility of witness statements as being hearsay unless those statements were made in open court or deposition with an

opportunity for cross-examination. On the other hand, pursuant to the Federal Rules of Evidence, after sufficient showing of reliability and trustworthiness, out of court statements, whether sworn or unsworn, might well be admissible. In a given case, the application of the Federal Rules of Evidence can thus easily lead to the submission of a case to a jury based upon "hearsay testimony" in circumstances where the case would not be submitted to the jury in the state court because of the hearsay rule. Accordingly, for this Court to give credence to the argument that the general acceptance standard should not be followed because of the potential effect on the outcome of diversity cases, this Court must necessarily conclude that the Federal Rules of Evidence relating to hearsay must be repealed. Similarly, the Court would need to repeal most, if not all, of the Rules of Evidence. The illogic of the position is obvious.

B. The General Acceptance Standard Would Not Significantly Impact The Outcome Of Diversity Cases Since The Overwhelming Majority Of The States Follow The General Acceptance Standard Or Require Reasonable Reliability As A Foundational Prerequisite To The Admissibility Of Expert Testimony

Suggestion has also been made that this Court should not follow the general acceptance standard because of the claimed rights of the various states to determine the outcome of cases within the confines of their state lines. While the state courts and state legislatures may possess the right to define the rules of evidence applicable to trials in the state courts, this Court possesses the sole authority to promulgate rules of evidence which are applicable to the federal courts. Indeed, one of the salutary purposes of jurisdiction based upon diversity of citizenship is to

ensure the fairness of trials between citizens of different states, thereby avoiding the potential of one state implementing rules which are unfair to citizens of other states.

Just as significantly, however, a clear pronouncement by this Court that the "general acceptance" standard prevails in the federal court would not lead to results, in the various states, which would be significantly inconsistent if the same cases were instead tried in the state courts.

Thirty states, some of which have adopted Rules of Evidence similar, if not identical, to Rules 702 and 703, have either expressly adopted the general acceptance standard or a rule of law which, in application, is comparable thereto, including: Alabama, Arizona, California, Colorado, Connecticut, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Washington, West Virginia and Wyoming.[1]

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[1]Snowden v. State, 574 So2d 960 (Ala. Crim. App. 1990); State ex rel. Collins v. Superior Court, 132 Ariz. 180, 196, 644 P.2d 1266, 1282 (1982); People v. Kelly, 17 Cal. 3d 24, 29, 130 Cal. Rptr. 144, 549 P.2d 1240 (1976); Stoczynski v. Livermore, 782 P.2d 834 (Colo. App. 1989); Moore v. McNamara, 210 Conn. 16, 30, 513 A.2d 660, 667 (1986); Harper v. State, 249 Ga. 519, 292 S.E.2d 389 (1982) (while rejecting the "Frye Rule", requires verifiable certainty); Wilson v. Clark, 84 Ill. 2d 186, 417 N.E.2d 1322 (1981) (citing FRE 703) and People v. Jordan, 103 Ill.2d 192, 469 N.E.2d 569 (1984); Noblesville Casting v. Div. of TRW, Inc., 438 N.E.2d 722 (Ind. 1982) and Cornette v. State, 450 N.E.2d 498 (Ind. 1983); Smith v. Deppish, 248 Kan. 217, 236, 807 P.2d 144 (1991); Bussey v. Commonwealth, 697 S.W.2d 139 (Ky. 1985) and Commonwealth v. Rose, 725 S.W.2d 588 (Ky. 1987); State v. Deville, 524 So2d 1334 (La. App. 1st Cir. 1988), writ denied, 531 So2d 263 and American Manufacturers Mutual Ins. v. General Motors Corp., 582 So2d 943 (La. App. 2d Cir. 1991); Reed v. State, 283 Md. 374, 381, 391 A.2d 364, 367 (1978); Croall v. Mass. Bay Transp. Auth., 26 Mass. App. Ct. 975, 526 N.E.2d 1320 (1988); People v. Young, 418 Mich. 1, 340 N.W. 2d 805 (1983) and Miller v. State Farm Mut. Auto Ins. Co., 168 Mich. App. 238, 424 N.W.2d 31 (1988); State v. Oslund, 469 N.W.2d 489 (Minn. Ct. App. 1991) and State v. Anderson, 379 N.W.2d (continued)

Another seventeen states, some of which have rejected the "Frye Rule" and some of which have not addressed the issue, have adopted rules of evidence substantially similar, if not identical, to Federal Rules 702 and 703, either by legislation or common law, and presumably would give great weight to this Court's interpretation of those rules, such states including: Alaska, Arkansas, Delaware, Florida, Hawaii, Idaho, Iowa, Maine, Missouri, Montana, New Hampshire, New York, North Carolina, Oregon, South Carolina, Texas and Vermont.[2]

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70 (Minn. 1985) (requiring "broad acceptance"); Comment to Miss. R.Evid. 702, citing Frye, states that adoption of Rule 702 did not relax the general acceptance requirement, with Hardy v. Brantly, 471 So2d 358, 366 (Miss. 1985) specifically requiring general acceptance; State v. Reynolds, 235 Neb. 662, 457 N.W.2d 405 (1990); American Elevator v. Briscoe, 93 Nev. 665, 671, 572 P.2d 534 (1977); Landrigan v. Celotex Corp., 127 N.J. 404, 417, 605 A.2d 1079 (1992) and Rubanick v. Witco Chemical Corp., 125 N.J. 421, 593 A.2d 733 (1991); State v. Trimble, 68 N.M. 406, 362 P.2d 788 (1961) and State ex rel. Human Services Dep't v. Coleman, 104 N.M. 500, 723 P.2d 971 (N.M. Ct. App. 1986); Stein v. Ohlhauser, 211 N.W.2d 737, 743 (N.D. 1973); Smith v. State, 656 P.2d 277 (Okl. Crim. App. 1982) and Robinson v. State, 677 P.2d 1080 (Okl. Crim. App. 1984), cert. denied 467 US 1246 (1984); Commonwealth v. Topa, 471 Pa. 223, 369 A.2d 1277 (1977); Powers v. Carvalho, 281 A.2d 298, 304 (R.I. 1971); State v. Dirk, 364 N.W.2d 117, 120-21 (S.D. 1985); Tenn. R.Evid. 703 and State v. Williams, 657 S.W.2d 405 (Tenn. 1983); Kofford v. Flora, 744 P.2d 1343, 1346 (Utah 1987) (requiring general acceptance or "inherent reliability"); State v. Lord, 117 Wn2d 829, 850, 822 P.2d 177 (1991); W.Va. R.Evid. 702 and 403 and State v. Woodall, 385 S.E.2d 253, 259 (W. Va. 1989); Buhrle v. State, 627 P.2d 1374, 1377-78 (Wyo. 1981) (requiring that pertinent "state of the art" support the opinion).

[2]Alaska R.Evid.; Ark. R.Evid. and Prather v. State, 307 Ark. 180, 820 S.W.2d 429 (1991); Del. R.Evid.; Fla. Evid. Code § 90.403 requirement of "probative value" and cases defining same, Kruse v. State, 483 So2d 1383 (Fla. 4th DCA 1986); Hawaii R.Evid.; Idaho R.Evid.; State v. Hall, 297 N.W.2d 80, 84-85 (Ia. 1980), cert. denied, 450 US 927 (1981) and State v. Nelson, 480 N.W.2d 900 (Ia. App. 1991); Maine R.Evid.; R.S.Mo. § 490.065 (1989); Mont. R.Evid.; N.Hamp. R.Evid.; Holshek v. Stokes, 505 N.Y. S.2d 664, 122 A.D.2d 777 (1986) and Hambsch v. New York City Transit Authority, 63 N.Y.2d 723, 469 N.E.2d 516 (1984) (incorporating requirements of FRE 703 by common law); N.Carol. Gen. Stat. § 8C-1; Oreg. R.Evid. (ORS 40.415); Howell v. PYA-Monarch, Inc., 344 S.E.2d 157 (S.C. Ct. App. 1986) and Campbell v. Parchal, 347 S.E.2d (continued)

Only three states, Ohio, Virginia and Wisconsin, follow the rule that the foundational prerequisite for expert opinions is that "one is willing to testify."[3]

Thus, notwithstanding contrary suggestions, the general acceptance standard, if followed by the federal courts, would not significantly effect the outcome of the same cases tried in the state courts since thirty states have adopted a rule identical or comparable to the general acceptance standard, thirty-five to thirty-eight states follow rules identical or similar to Rules 702 and 703, with only three states following the approach suggested by Petitioners.

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892 (S.C. Ct. App. 1986) (adopting language of FRE 703 by common law); Tx. R.Evid and Texas Farm Bureau Mutual Ins. Co. v. Baker, 596 S.W.2d 639 (Tex. Civ. App. - Tyler 1980); Vermont R.Evid.

Amicus has not attempted to numerically quantify those states which have both accepted the "general acceptance standard" and adopted Rules comparable to 702 and 703, nor has Amicus attempted to numerically quantify those states which have rejected the "general acceptance standard", while adopting Rules comparable to 702 and 703. However, it is significant to note, without regard to whether the general acceptance standard has been accepted or rejected by those states, according to Judge Weinstein and Professor Berger, at least 28 states have adopted Rule 702 without change, at least six states have adopted Rule 702 with minor changes, at least 26 states have adopted Rule 703 without change, and another eleven states have adopted Rule 703 with minor changes. 3 Weinstein's Evidence, 702-64 thru 95 and 703-40 thru 57. Since the date of the last supplementation to the work of Weinstein and Berger, Missouri (and possibly other states) has been added to the count of those states which have adopted Rules essentially identical to Rules 702 and 703. R.S.Mo. § 490.065 et seq. Thus, 35 states have adopted Rules which are identical or substantially identical to Rule 702 and 38 states have adopted Rules which are identical or substantially similar to Rule 703.

[3]State v. Pierce, 61 Ohio St. 3d 190, 597 N.E.2d 107 (1992); O'Dell v. Commonwealth, 234 Va. 672, 695-96, 364 S.E.2d 491, 504 (1988); State v. Walstad, 119 Wis. 2d 483, 515-19, 351 N.W.2d 469, 485-87 (1984).

CONCLUSION

Rules of evidence, like any other rule of law, should serve the broad societal interests of evenhanded, consistent, and predictable application of legal rules, founded upon bedrock principles rather than in the proclivities of individuals. A rule of evidence which permits expert opinions based upon tenets or techniques not generally accepted by the scientific or medical community creates unpredictability of the duties owed by one citizen to another and establishes standards of care based upon individual proclivities, rather than societal norms. Interpreting the Federal Rules of Evidence so as to require general acceptance within the scientific or medical community as a foundational prerequisite to the admissibility of expert opinions would ensure fairness, predictability, and a uniform guide against which citizens of the United States can measure their conduct. Such a standard would not discourage scientific or medical development, while adoption of a rule of evidence which has as its sole foundational prerequisite "a willingness to testify" would dramatically reduce scientific and medical development to the grave detriment of the public. The general acceptance standard would have no greater effect on the outcome of diversity cases than does any other Federal Rule of Evidence and would not significantly change the outcome of cases tried in the federal courts, as contrasted to those tried in the state courts, since the overwhelming majority of the states follow the general acceptance standard or require reasonable reliability as a foundational prerequisite to the admissibility of scientific or medical testimony.

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Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,

Petitioners,

—v.—

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF THE NEW ENGLAND JOURNAL OF MEDICINE, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, AND ANNALS OF INTERNAL MEDICINE AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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January 19, 1993

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

No. 92-102

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,

Petitioners,

—v.—

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF THE NEW ENGLAND JOURNAL OF MEDICINE, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, AND ANNALS OF INTERNAL MEDICINE AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

INTEREST OF THE AMICI CURIAE*

This brief is submitted on behalf of the New England Journal of Medicine, Journal of the American Medical Association and Annals of Internal Medicine, three of

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* Counsel for the parties have consented to the filing of this brief, and letters of consent have been filed separately with the Clerk.

the world's foremost medical journals, concerning the issue of peer-review. One of the factors that contributes to the high professional standing of these journals is the very rigorous standard of accuracy and reliability they apply to the articles they publish—a standard protected by the peer-review process. Amici submit this brief, in the classic tradition of *amicus curiae* briefs, to familiarize the Court with, and endorse, the uniformly accepted standards of "good science" including publication subject to peer-review. While this brief is submitted in support of respondent concerning the importance of peer-review to good science, Amici take no position on the ultimate issue of whether Bendectin causes birth defects.

DISCUSSION

I. Good Science, The Minimum Standard Of Credibility For Any Research, Requires Peer-Review And Publication

"Good science" is a commonly accepted term used to describe the scientific community's system of quality control which protects the community and those who rely upon it from unsubstantiated scientific analysis. It mandates that each proposition undergo a rigorous trilogy of publication, replication and verification before it is relied upon. Scientific advances occur, in part, because dissemination of results by publication allows scientists to learn about and critique the reported research. In this way, scientists may expand upon what has already been achieved.[1] Peer-review has long been

1 Scientific research is conducted by building upon, and expanding, the research previously performed. As discussed in Section IV, *infra*, if the initial research reported in publications is not a secure block upon which to build, further research will lack a proper foundation.

utilized by technical journals to assure and improve the quality of the information they disseminate and is an essential prerequisite to publication.

Peer-review focuses on the methodology, analysis and results recited in an article in an attempt to weed out error (*e.g.*, from observer bias, improper statistical analysis, insensitive methods, carelessness and failure to recognize and control for confounding variables) and to assure that the text of an article is complete so that readers may judge the work for themselves. In this way, the peer-review process not only reduces the opportunity for reporting errors but assists in improving the quality of the written report and impels scientists to raise the standards of research and writing. *See* Relman and Angell, *How Good is Peer Review?*, 321 New Eng. J. Med. 827, 828 (1989). Its role in the publication process is nonetheless limited. Peer-review does not (and cannot) control what is selected by the editors of a journal for publication; nor can it guarantee that reported results are correct. Its role is to promote the publication of well-conceived articles so that the most important review, the consideration of the reported results by the scientific community, may occur after publication.

Good science requires that a proposition be supported by experimental data, be reduced to writing, and be published after undergoing peer-review *prior to* any reliance thereon. The published article should include enough information about the design, methodology and analysis of the reported experiments or observations to permit other scientists to duplicate and verify the results as a basis for further study. Defense of a proposition before

qualified peers—both in the form of peer-review and post-publication comments such as Letters to the Editor (*see* note 11, *infra*)—is the bedrock of the scientific credibility which justifies, *inter alia*, a court's reliance upon the expression of expert scientific opinion in making findings of fact. Under certain circumstances, an expert's opinion need not undergo peer-review unless the expert seeks to offer a view inconsistent with that previously published in peer-reviewed journals. Where the expert seeks to do so, she must submit the basis of the opinion for peer-review and publication before it is credible.[2] Unlike the biases inherent in litigation—which may skew an expert's opinion or results to benefit one party over another—good science is not primarily concerned with what the results may turn out to be, but rather with the accuracy and reliability of the experimental methodology and data by which they are reached.

In many circumstances, failure to seek peer-review and publication of research or results calls into question not only the ultimate conclusions reached, but also the methodology employed in conducting the research or analyzing the results.[3] This is because unwillingness to

2 Amici do not suggest that all propositions propounded by an expert witness in a lawsuit must be peer-reviewed before they can be relied upon. There are situations, such as the application of an accepted theory to specific facts, in which peer-review might not be necessary or even appropriate. However, propositions propounded by an expert ought to be based upon, or consistent with, data or methodology published in peer-review journals, whenever such are available.

3 In some instances, researchers elect to make the first disclosure of their research or results through other means of publication, such as at conferences or to governmental panels, prior to publication in a journal. This is not necessarily inconsistent with the peer-review process, although it can affect the editorial decisions of some peer-reviewed journals which do not publish previously disseminated research results.

subject one's methodology to review—both during peer-review and by the scientific community after publication—stands as a telling admission that the standards of reliability associated with the peer-review process may not have been met.

Of course, it is unreasonable to expect all scientific analysis to be published in a peer-reviewed journal.[4] However, for certain branches of science, such as biomedical science and, more particularly, epidemiology, bio-statistics and dysmorphology, an expert's conclusions and opinions generally are not relied upon until they have been reduced to writing and published after review by a panel of experts. *See* Relman, *Publishing Biomedical Research: Roles and Responsibilities*, 20 Hastings Center Rep. 23 (May/June 1990). This review—a "cross-examination" of the methodology and analysis by those versed in the technical issues—either establishes the proposition as one which reasonably may be relied upon, or, in the alternative, suggests further work (*e.g.*, revision of the article) thereby protecting the integrity of science.

II. Peer-Review As A Safeguard For The Reliability Of Scientific Propositions Originated in the Mid-18th Century

The origins of peer-review are frequently traced to 1752 when the Royal Society of London, a medical society, began publishing *Philosophical Transactions* and established a "Committee on Papers" to review articles submitted for publication. Kronick, *Peer Review In*

4 For instance, it would be unreasonable to expect that every expert witness testifying at a trial would have submitted and published the opinion at issue, when it may be of no interest outside the context of the case. See note 2, *supra*.

Eighteenth-Century Scientific Journalism, 263 J. A.M.A. 1321 (1990), *citing The Records of the Royal Society of London* (1940 4th ed.) and Ziman, *Information, Communication, Knowledge*, 224 Nature 318 (1969). The Committee, which consisted of at least five members, could call on "any other members of the Society who are knowing and well skilled in that particular branch of Science that shall happen to be the subject matter of any paper which shall be then to come under their deliberations." *Id.* Accordingly, the Committee could solicit pre-publication reviews of a paper from anyone knowledgeable in the field.[5]

It was not until the 19th century, however, that medical journals not affiliated with professional societies came into existence. Burnham, *The Evolution of Editorial Peer Review*, 263 J. A.M.A. 1323, 1324 (1990). The early medical journals were written primarily by their editors or employees (much like newspapers and magazines), and outsiders were not requested to review the articles. Similarly, scientific journals were published as the official record of research institutes and contained articles generated internally, not subject to outside review.

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5 Before the establishment of the Royal Society of London's Committee on Papers, the Royal Society of Edinburgh stated a similar editorial policy in the preface to its 1731 *Medical Essays and Observations*. That policy called for a form of peer-review very similar to that employed today:

> Memoirs sent by correspondence are distributed according to the subject matter to those members who are most versed in these matters. The report of their identity is not known to the author. Nothing is printed in this review which is not stamped with the mark of utility.

Id. (citing 1 *Essais et Observations de médecine de la Société d'Edinbourg* (1740)).

This practice began to change in the late-19th and early-20th centuries when physicians began to specialize in particular fields, a process which spawned a demand for specialized journals. Peer-review by outsiders was nevertheless slow to take hold because many of these journals were personal publications of dominant authors. *Id.*

While many editors were avoiding peer-review in the early 20th century, other prominent editors embraced it, notably those at the *British Medical Journal*. *Id.* at 1325. Still other journals were adopting modified peer-review approaches, such as employing in-house reviewers. For example, when *Surgery, Gynecology and Obstetrics* was founded in 1905, the editor encouraged outside authors to submit articles but wrote that in-house experts would review all articles before publication. Similarly, book publishers recognized the need for peer-review as early as the 19th century and actively sought outside advice on, and review of, book manuscripts in technical fields.[6] *Id.* In the United States, journal editors did not widely adopt peer-review as an integral part of the publication process until after World War II, when a large number of United States medical journals began to adopt the practice. *Id.*

The history of the development of peer-review is not completely documented, and there are many gaps in the record of its evolution prior to World War II. It is clear, however, that the process of peer-review and publication has evolved along with science, and more particularly biomedical science. There can be no doubt that the use

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6 Those publishers, unlike the editors of medical journals, were lay people not expert in the field; so presumably they did not feel qualified to review a technical manuscript. *Id.*

of peer-review by journals to establish the credibility of articles has played a major role in the huge advances that have occurred in scientific and medical research since World War II. (Indeed, it is notable that the briefs of petitioners and many of the Amici supporting them rely heavily on articles published in peer-reviewed journals.) Thus, scientists in all disciplines have recognized the importance of peer-review and publication in developing research which may be relied upon, and so too should this Court.

III. The Peer-Review Process

The publication and peer-review process begins when an article is received by a journal. Articles are usually submitted without solicitation, and a journal's editor pre-screens them to determine if minimum criteria for publication are satisfied. (For example, the editor examines whether the subject matter is relevant to the journal's readership and whether the article is a repetition of prior publications.)[7]

The vast majority of the articles received by a journal which have not been initially rejected by the screening process are then submitted to a panel of outside experts selected on the basis of the paper's content. Typically, a journal maintains its own roster of qualified reviewers, often listing thousands of experts, and selects at least

7 At this stage, by way of example, the New England Journal of Medicine rejects about five to ten percent of the almost 4,000 submissions it receives each year. *The Journal's Peer-Review Process*, 321 New Eng. J. Med. 837, 838 (1989); *see also* Relman, *Peer Review In Scientific Journals—What Good Is It?*, 153 W.J. Med. 520 (1990). The Journal of the American Medical Association, on the other hand, rejects almost 40% of the articles it receives during the preliminary screening.

two for each article. The identities of the reviewers are not required to be disclosed to the author under the peer-review system used by most journals, since it is believed that this frees the reviewers to be as critical and candid as is appropriate without fear of retribution or bias. Relman, *Peer Review In Scientific Journals—What Good Is It?*, 153 W.J. Med. 520 (1990); Relman, *Anonymous Reviews Are Much More Likely To Be Forthright In Their Criticism, Regardless Of The Status Or Reputation Of The Author*, 2 J. of N.I.H. Res. 19 (1990). In addition to the outside reviewers, many journals, such as the Annals of Internal Medicine, also use in-house associate and technical editors who are expert in the relevant fields to review an article.

Once the outside reviewers have completed their assessment, typically within three weeks, they send their two part written reviews to the journal's editorial staff. In the first part, each reviewer provides identifying and background information and an opinion on whether the article should be published, the priority for publication and the article's overall merit.[8] This portion is retained by the editor and not sent to the author. The second part contains the reviewer's itemized substantive comments on the article's content, and a copy of this part is usually provided to the author.[9]

The reviewers' principal function is to identify any analytical problems in an article, as well as inconsistencies, ambiguities or gaps in the stated facts or anal-

8 This part also solicits any information that might indicate the reviewer's bias or any conflict (financial or otherwise) concerning the article or its author.

9 A sample review form used by the Journal of the American Medical Association is reprinted as Appendix A.

yses. In this way, they try to make sure that an author neither overstates nor understates the work or results. However, the reviewers "are consultants, not arbiters of publishability. Peer review is not a straw vote among referees but rather a source of information and technical advice to the editors, who should make the final decision." Relman, *Peer Review In Scientific Journals — What Good Is It?*, 153 W.J. Med. 520, 521 (1990). In advising an editor, the reviewers will indicate whether the article should be published as is, needs revision but should then be published, needs revision and then should be re-reviewed, or should be rejected. Typically, an editor will require an author to revise the article notwithstanding the results of peer-review; and the final decision on whether to publish an article is the editor's, often based upon a number of factors beyond the article itself such as space limitations, timeliness and priority.[10]

As previously discussed, peer-review and publication does not end the scientific inquiry. Indeed, the mere act of publication frequently provokes scientific critique of the article by readers, who often submit Letters to the Editor commenting on the strengths or weaknesses of the work and its implications.[11] Authors almost always

10 Many journals, including Amici, allow an author to dispute any technical or scientific reason for an article's rejection. The author may, for instance, request a new review by other reviewers. However, rejections for non-technical reasons (*e.g.*, repetition of a prior publication) are usually final. Rejected articles typically are resubmitted to other journals by their authors, where they are usually published. *See*, *e.g.*, note 12, *infra*.

11 An important part of every peer-reviewed publication is its forum for questions and/or comments from its readers, usually a Letters to the Editor section. For instance, The International Committee of Medical Journal Editors' "Uniform Requirements for

respond in the same column with additional comments expanding upon or explaining a point in the article. In some instances a letter can lead to corrections or retractions, which then become part of the available scientific literature for further study.

IV. Peer-Review Focuses On The Methodology Reported And The Analysis Of The Results

Peer-review does not entail an audit of the research reported in an article. The author-researcher must be relied upon to accurately and honestly report what occurred or was observed during research, and no review of a manuscript can analyze the accuracy or honesty of the reported observations. "Reviewers cannot, after all, watch the experiments being performed." Relman and Angell, *How Good is Peer Review?*, 321 New Eng. J. Med. 827, 829 (1989). Accordingly, it is not the province of peer-review to certify reported results or prevent fraud; and while it is reasonable to rely upon peer-review as validating the reported methodology or analysis and to confirm that the conclusions are justified by the data, it is unreasonable for the process to do more.

Because peer-review does not, and cannot, inquire into whether the authors actually did what they report, the reviewers cannot assure the readers of the truth of the ultimate conclusion contained in an article. Accord-

Manuscripts Submitted to Biomedical Journals," which have been agreed to by over 400 of the leading journals worldwide, specify that:

> All biomedical journals should have a section carrying comments, questions, or criticisms about articles they have published and where the original authors can respond.

Statements from the International Committee of Medical Journal Editors, 265 J. A.M.A. 2697, 2698 (1991).

ingly, peer-review should neither prevent the publication of articles on the "cutting-edge" of science nor limit the conclusions expressed. It asks only that the conclusions be appropriately based upon good evidence—indeed, it is the hope of a journal editor to publish "cutting edge" articles based upon proper experimental methodology and data, thereby boosting the journal's prestige.[12] Science is the ever-evolving search for elusive truths—with each new discovery everything previously known must be reevaluated. Thus, new scientific breakthroughs in the search for truth, whether Galileo's heliocentrism or the discovery of a treatment for AIDS, are embraced and welcomed by all true scientists; and so too are smaller steps toward the discovery of scientific truths. However, if the new "discovery" has not been reached by good science, including the process of publication and peer-review, then it is not reliable and should not be used by others in the reevaluation of what is known.

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12 In rare instances, reviewers have indicated that an article is not acceptable because it is contrary to "what everybody knows." Horrobin, *The Philosophical Basis of Peer Review and the Suppression of Innovation*, 263 J. A.M.A. 1438, 1440-41 (1990). Normally, such a suggestion is rejected by the editor. In those rare instances in which an editor declines to publish a paper for this reason, the article is usually published in another journal. Horrobin (*id.*), for instance, cites several examples of articles that were not published in the first journal chosen by the author because of, in part, the results of peer-review (sometimes the rejections are justified but in other cases they may have been the result of inappropriate conduct by competing or jealous peers—similar to Galileo's treatment by those with a non-scientific agenda). However, in all of these cases the articles were eventually published in responsible journals and several resulted in Nobel Prizes based upon the publications (much to the embarrassment of the editors who had rejected the articles). *Id.* At the present time there are over 100,000 scientific and medical periodicals and journals available for such publication world-wide.

A cogent example of the importance of peer-review occurred in March, 1989, when the scientific community was rocked by reports that a method for cold fusion finally had been found. In theory, cold fusion allows nuclear energy to be harnessed without creating radioactive waste by combining atoms instead of destroying them; but for years scientists had tried to reduce the theory to practice without success. Because of the importance of their "discovery," the two researchers who announced it decided to by-pass the usual peer-review and publication process and go public with their results. Millions of dollars and research hours were then invested by others to support continued research. Although the two researchers initially refused to disclose the details of their original experiments, it has now been determined that what the researchers thought was cold fusion was really a series of errors compounded by their failure to follow the good science of peer-review and publication. *See* Broad, *Cold-Fusion Claim is Faulted On Ethics As Well As Science*, N.Y. Times, March 17, 1991, at 1, col. 1; *see also* Hall, *Perpetual Motion It Isn't* (Book Review), L.A. Times, May 12, 1991 at 11 (reviewing Close, *Too Hot to Handle: The Race For Cold Fusion*). Amici submit that if the researchers had submitted their results for peer-review and publication, as mandated by good science, their error would have been recognized before millions of dollars and much time and effort were wastefully expended based upon invalid methodology and analysis resulting in incorrect conclusions. *See* Broad, *Cold Fusion Still Escapes Usual Checks of Science*, N.Y. Times, October 30, 1990, at 1, col. 1.

On the other hand, recently many advances have been made in superconductivity, which allows the transmis-

sion of energy over long distances with virtually no loss due to resistance. Those researchers diligently followed the precepts of peer-review and publication and achieved a major breakthrough. *See* Van, *Superconductivity Nears Practical Use*, Chicago Trib., February 10, 1992, at Business 1; *see also* Browne, *Chemists' New Toy Emerges As Superconductivity*, N.Y. Times, September 3, 1991, at C-1, col.1.

The virtues of peer-review in ensuring proper methodology and analysis of research are obvious. Proper prepublication peer-review is the only safeguard that exists to establish reliability of articles and prevent publication of incorrect conclusions.

V. Peer-Review's Role In Determining The Admissibility Of Scientific Propositions

The question before the Court is not the role of peer-review and publication in scientific research—science itself has already determined its paramount importance. The Court must determine the role of publication in peer-reviewed journals as part of good science under the rules of evidence.

At issue is whether, under the Federal Rules of Evidence, a court may exclude from evidence, or find insufficient, an expert's opinion if it contradicts an existing body of scientific work published in peer-reviewed journals and others in the field would not recognize it as having been validly reached, *e.g.*, by good science employing the checks of publication subject to peer-review. As recognized by the Ninth Circuit (951 F.2d 1128, 1131), as well as the First, Fifth and D.C. Circuits,[13] a court should look to whether the proposition

13 *See Christophersen v. Allied Signal Corp.*, 939 F.2d 1106 (5th Cir. 1991) (*en banc*), *cert. denied*, 112 S. Ct. 1280 (1992);

being set out by an expert is in accordance with published scientific data whenever available—data developed by good science, utilizing publication and peer-review standards which exist independent of the biases inherent in litigation—before finding the opinion admissible or sufficient to establish a *prima facie* case. It is elementary that this inquiry should not be governed simply by the ultimate conclusion reached by the expert, but by the methodology and analyses used in reaching it in the context of any already published results.

Equally important to good science, and therefore the rules of evidence, is that the converse is not true: Results which have survived the peer-review process are not immune from further review or attack. Peer-review does not guarantee that results are error free. Publishing research results in a peer-reviewed journal does not end the research inquiry; it merely advances the knowledge with which research is conducted. The reported results become a building block upon which further research is based; and subsequent research, such as a replication of or attack on the initial results, forms the basis of continuing study once published in a peer-reviewed journal.

Subsequent work may seek to disprove the prior analysis or inquire into the researcher's methods or results. However, the new research must also be conducted under the rigors of good science before it may be relied upon. Moreover, research to prove a new proposition or refute earlier work—and thereby invalidate both the work and anything that builds upon it—must also be peer-reviewed, although it must be scrutinized more rigor-

Kropinski v. World Plan Executive Council—U.S., 853 F.2d 948, 956 (D.C. Cir. 1988); *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190, 1194-95 (1st Cir. 1987).

ously than confirmatory research because of the inherent difficulties that would result if incorrect conclusions were relied upon.

The goal of publication and peer-review, as part of good science, is to prevent premature reliance on certain propositions by the scientific community before the supporting evidence has been reviewed by a panel of expert peers and published for all to see; the goal of the rules of evidence, as part of due process, is to prevent premature reliance on certain propositions by a fact finder before it has been found probative, relevant and reliable. Neither guarantees the accuracy of the information or assesses its weight in finding the truth. But both establish a threshold level of reliability. In either situation it would be imprudent to rely upon a proposition before, at a minimum, it has been passed upon for plausibility.

The only mechanism available to assess the credibility of a scientific opinion crucial to the question of liability, independent of the biases of litigation, is to confirm that the opinion was reached by good science, *e.g.*, based upon published evidence that has been peer-reviewed, and then subject to replication and verification. Accordingly, were this Court to repudiate peer-review—an action which Amici strongly oppose—there would be no objective standard for a court to apply in evaluating the credibility of a scientific opinion. Peer-review and publication of scientific data and conclusions, simply put, are the only available non-biased checks on scientific opinion available to the courts and should, therefore, be employed to the extent feasible.

January 19, 1993

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MEDICAL ASSOCIATION, and
ANNALS OF INTERNAL MEDICINE
as *AMICI CURIAE*.

APPENDIX

[LETTERHEAD OF THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION]

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Enclosure

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The Journal of the American Medical Association

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Data valid?	❑	❑	❑	❑
Conclusions reasonable?	❑	❑	❑	❑
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Writing clear?	❑	❑	❑	❑
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Supreme Court, U.S.
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No. 92-102

IN THE
Supreme Court of the United States
OCTOBER TERM, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,
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v.

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Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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BRIEF AMICUS CURIAE OF PROFESSOR ALVAN R. FEINSTEIN IN SUPPORT OF RESPONDENT

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January 19, 1993

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

No. 92-102

WILLIAM DAUBERT and JOYCE DAUBERT,
Individually and as Guardians Ad Litem for
JASON DAUBERT, and ANITA DE YOUNG, Individually
and as Guardian Ad Litem for ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

**On Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit**

BRIEF AMICUS CURIAE OF PROFESSOR ALVAN R. FEINSTEIN IN SUPPORT OF RESPONDENT

INTEREST OF AMICUS CURIAE

Alvan R. Feinstein, M.D. is Sterling Professor of Medicine and Epidemiology at the Yale University School of Medicine, where he is also Director of the Clinical Epidemiology Unit. He is the author of texts entitled *Clinical Judgment*, *Clinical Biostatistics*, *Clinical Epidemiology* and *Clinimetrics*. He is co-editor of the respected *Journal of Clinical Epidemiology*. He has contributed hundreds of articles to the medical and scientific literature over the past 40 years, and helped to pioneer the field of Clinical Epidemiology. A more complete biog-

raphy of the amicus appears in the Appendix to this brief.

Dr. Feinstein submits this brief in support of Respondent Merrell Dow Pharmaceuticals, Inc. to answer the Brief *Amici Curiae* of Professors Kenneth Rothman, Noel Weiss, James Robins, Raymond Neutra and Steven Stellman, in Support of Petitioners (collectively, "Rothman, *et al.*"). For the past quarter-century, Dr. Feinstein has been at the forefront of the field of clinical epidemiology and has advocated developing scientific standards for conducting epidemiologic investigations. Dr. Feinstein disagrees with Rothman, *et al.*'s "free-for-all" approach to the admission of scientific evidence in a court of law and its implicit evisceration of scientific standards. He submits this brief to apprise the Court of the opposing viewpoint, which insists that the standards of scientific and intellectual discipline be recognized and observed, and that scientific standards be maintained and respected when scientific evidence is used in courts of law.[1]

SUMMARY OF ARGUMENT

I have read the Brief *Amici Curiae* of Professors Kenneth Rothman, Noel Weiss, James Robins, Raymond Neutra, and Steven Stellman, in Support of Petitioners ("Rothman Brief"). I have some profound disagreements with its concepts and recommendations. I understand that the issue before this Court concerns the proper role of judges and courts in controlling the flow of scientific evidence to juries in litigation. The approach suggested by Rothman, *et al.* appears to leave no room for the application of suitable scientific standards in evaluating the worth of scientific evidence in litigation. Rothman, *et al.*'s criticisms of the lower courts' decisions[2] entirely miss the point that the matter at issue is not recent scien-

[1] Counsel to the parties have consented to the filing of this brief. Letters of consent have been filed with the Clerk.

[2] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 727 F. Supp. 570 (S.D. Cal. 1989), *aff'd*, 951 F.2d 1128 (9th Cir. 1991).

tific discovery which can be weighed and evaluated by a jury of scientists, who might well wish to have "all the facts." The information is to be weighed by a jury of lay persons who are subject to understandable confusion by epidemiology. The suggestion that judicial safeguards be abandoned would lead to intellectual anarchy and decision-making by juries based upon suspect or highly unreliable data. Judicial screening of proposed expert evidence is essential to the legal process.

Peer review serves a similar, vital purpose in the scientific community. Although peer review alone does not guarantee the soundness of research, it certainly increases the likelihood that the work is trustworthy because it has been subject to the harsh light of critical appraisal and public exposure. Discarding peer review as a test for scientific reliability would make the judicial process less reliable to the detriment of all. Meta-analysis and re-analysis, techniques urged by Rothman, *et al.*, are not themselves invalid methods. They are, however, subject to abuses, distortions, and inaccuracies, which make their review by peers, prior to unguarded disclosure to a jury, vitally important.

Finally, although it is true that "statistically significant" data are not the only epidemiologic data upon which scientists base inferences, jurors are not themselves practicing scientists. Therefore, there are good reasons for limiting epidemiologic proof in the courtroom to evidence which has met accepted scientific and statistical standards for numerical stability. The tool of "confidence intervals" is not a substitute for the scientific standard of "statistical significance." Confidence intervals can replace P values as the main tool for measuring numerical stability, but they have strengths and weaknesses which are analogous to those of P values. If a specific boundary, such as 90% or 95%, is not set for the confidence levels, the stability of the numbers becomes untrustworthy, and the investigator can arrange the intervals to show almost anything that is desired.

ARGUMENT

I. JUDICIAL STANDARDS ARE NECESSARY TO ENSURE THE TRUSTWORTHINESS OF SCIENTIFIC EVIDENCE.

My first comments refer to the implicit proposal by Rothman, *et al.* that the judge in a legal proceeding act as a mere conduit rather than a careful filter in transferring scientific information to the jury. Rothman, *et al.* say that if they were "on a jury in a civil trial, *amici* would wish to have access to the same sources we consult as practicing scientists. We would want to know all the facts, not just the truncated 'consensus'." Rothman Brief at 13. Thus, Rothman, *et al.* apparently would want anything and everything to be presented directly to the jury, without the judge making any prior appraisal of suitability or pertinence.

I vigorously disagree. First, the phrase "truncated 'consensus' " implies that the published literature is monolithic in viewpoint and grossly inadequate. This implication is false. I do not know of a single disputed issue, particularly in the field of epidemiology, that lacks publications from both sides of the argument (and sometimes from more than just two sides). The total array of publications may be unbalanced in one direction or the other, and the degree of imbalance may be affected by the "consensus" viewpoint. Nevertheless, alternative views are there; they can be found; and they can be introduced into the courtroom. One need not and should not, as Rothman, *et al.* suggest, utilize "informal exchanges," "conversations" and other unpublished material to provide information for the parties' contentions in a legal proceeding. Such information, untested by the rigors of the public forum provided by publication, may sometimes be essentially hearsay and gossip, rather than sound science.

Secondly, Rothman, *et al.* seem to forget that the members of a jury are not "practicing scientists". They are seldom familiar with the intricacies of the scientific process; they are unaware of the substrata or characteristics of scientific disputes, and, understandably, they have great difficulty comprehending many of the complexities. Thus, Rothman, *et al.* can easily distinguish the differences between P values and confidence intervals, between substantive (or "quantitative") significance and "statistical" significance, between scientific inference and statistical inference, between a random sample and a randomized trial. Most scientists and almost all physicians, however, have great difficulty in grasping these distinctions. How then is a jury of "laymen" supposed to grasp and apply these concepts unless the judge acts as an active guide, translator, "editor", or referee rather than as passive conduit? I understand that a principal test for the admissibility of expert evidence is that it "assist the trier of fact to understand the evidence or to determine a fact in issue . . ." F.R.E. 702. The admission of "all the facts," as Rothman, *et al.* suggest, untempered by sound guiding principles, would contribute only to confusion or distortion, not understanding.

Rothman, *et al.* have transposed, to a completely inappropriate arena, their admirable thought that scientific information of all kinds, particularly dissenting opinions, should be available for evaluation. The courtroom is not the forum for the advancement of scientific knowledge. It is where juries of the participants' peers assign responsibility for the causation of injuries, not where practicing scientists seek new discoveries.

Finally, Rothman, *et al.* set no standards, give no guidelines, and present no criteria for evaluating the "sources (they) consult as practicing scientists". With no limitation on the kinds of sources that are acceptable, the judge is apparently supposed to allow anything to be examined, including the unpublished re-analysis or meta-

analysis from a "scientific expert" who is no more than a "professional witness".

Because Rothman, *et al.* are presumably thoughtful scientists, I doubt that they have thoroughly considered the consequences of what they propose. Discontent with the existing scientific standards, they apparently seek to regress to an era when no standards at all existed. They suggest that their position is supported by "a large community of respected epidemiologists." I would be surprised if that statement were true. Most members of the "community" of scientists would reject the intellectual anarchy that is being proposed.

The Court's decision in this case will not "alter the role of epidemiological concepts in science" as Rothman, *et al.* suggest. Scientists, not courts, will ultimately determine that role. However, the Court's decision will determine whether scientific standards, designed to ensure the reliability and acceptability of scientific results, can be ignored by scientific witnesses in presenting their testimony to lay juries.

Like editors and reviewers who are the judges in science, legal judges are imperfect. I am certain that they sometimes err or misinterpret. Their rulings are sometimes reversed on appeal, just as the original verdicts of editors and reviewers at one professional journal may be reversed by those at another. Nevertheless, despite their imperfections, judges are the best thing society has available to set and maintain reasonable standards for what is admissible scientific evidence in a court of law.

I do not believe that society, science, or law will be served if judges are rendered unable to carry out that crucial function.

II. PEER REVIEW AND PUBLICATION ESTABLISH NECESSARY STANDARDS AND RIGOROUS DISCIPLINE FOR THE SCIENTIFIC COMMUNITY.

As someone who has regularly published dissents from the "consensus" and the "accepted wisdom," I completely agree with the eloquent assertion by Rothman, *et al.* that "close and repeated questioning of all available scientific information . . . is the engine of scientific progress and the determinant of . . . scientific truths.' Rothman Brief at 12. I also agree with their remark that "peer-reviewed publications have never functioned as . . . sole guarantors of scientific truth." *Id.*

On the other hand, I deplore their failure to offer any better substitute for scientific acceptability than "informal exchange" by "practicing scientists." As an editor, investigator, and author, I know that the peer-review process has many flaws. So does a democratic system of government. But like democracy, peer-review is the best system we have available. It offers the hope, and often the guarantee, that a minimum standard will be maintained for scientific (and literary) discipline.

I doubt that Kenneth Rothman, as editor of a professional journal, automatically accepts and publishes whatever is sent to him; and I know of no other editor (including myself) who would do so. Editors and reviewers are occasionally wrong in their decisions. Even the most prestigious and respected scientific journals have rejected work that later won a Nobel prize, and have accepted work that turned out to be fraudulent, erroneous, or misleading.

Nevertheless, serious scientists know that their work does not become scientific information until it is published. If they believe the work is worthwhile but unappreciated by a set of reviewers at a particular journal, the authors will try elsewhere (perhaps after making some improvements or other changes suggested by the reviewers). Thus, if the work is rejected by Journal A,

the authors try Journal B. If Journal B says "no," they try Journal C. They may go on to many more journals, but eventually they get the work published. If the work is worthwhile, somewhere in the scientific "establishment", the authors will find an editor and/or reviewer who will appreciate—or at least tolerate—it.

All of the famous scientific "heretics" and "nonconformists," from Galileo onward, who had initial difficulty getting their work accepted by the "establishment" that was the "peer-review process" of their era, nevertheless persisted and managed to get the work published. Without that persistence *and publication*, we would not know of the work today.

This is the reason why responsible scientists will almost always decline to rely upon work that has not been published. The absence of publication means that the author has not had the intellectual discipline and self-respect, and enough "confidence" in the work itself, to get it published. Of course, a great deal of valuable information can be involved in the "informal exchanges" of meetings, conversations, letters, or even gossip among scientists. If the information is serious and valuable, however, it becomes expressed more formally in the true "currency" of scientific exchange: publication. An author or investigator who is unable or unwilling to get his work accepted in the fundamental primary "court" of scientific publication should surely not expect to get it accepted secondarily in a court of law.

III. RE-ANALYSIS IS AN ACCEPTABLE SCIENTIFIC METHOD, BUT IT, TOO, SHOULD BE SUBJECTED TO ESTABLISHED SCIENTIFIC STANDARDS AND THE RIGORS OF PEER REVIEW.

The argument that Rothman, *et al.* offer about "re-analysis" is confusing because it encompasses two different activities: (1) re-analysis, discussed in this section, is what occurs when the data or results *for a single study*

are re-appraised; (2) meta-analysis, discussed in the next section, is what occurs when results for a series of studies are "pooled," with conclusions being drawn from the combined aggregate of data.

An effective re-analysis can be done if the analyst has complete access to all the original data of the individual study. For example, the Food and Drug Administration regularly re-analyzes (usually during supervisory checking) the huge collection of original data submitted by pharmaceutical companies as part of new drug applications. In most instances, however, the person doing a re-analysis works not with the original data, but only with the excerpts and summaries that have been published in the scientific literature.

From the available published information, the re-analyst can explore things in diverse ways: putting the cart before the horse, comparing the size of the cart wheels and the number of horses, speculating about what would happen if the cart were larger, had more wheels, or more horses, and so on. Nevertheless, the re-analysis is almost always limited to what was available in the original published report.

This constraint does not prevent re-analysis from being done and from sometimes being quite useful, provided that the analyst has been suitably careful to avoid distortion, and to maintain acceptable scientific discipline in obtaining, presenting, and publishing the results. For example, some years ago, several colleagues and I published, in the *Journal of the American Medical Association*,[3] a re-analysis that demonstrated the fallacies of a study that had originally been published in the *New England Journal of Medicine*. After this re-analysis, and after the appearance of subsequent research that contra-

[3] A. Feinstein, R. Horwitz, W. Spitzer, R. Battista, "Coffee and Pancreatic Cancer: The Problems of Etiologic Science and Epidemiologic Case-Control Research," 246 *Journal of the American Medical Association* 957 (1981).

dicted the original study, and after repeating his own study, the original author eventually "admitted" the error.

I therefore agree with Rothman, *et al.* that re-analysis can furnish acceptable scientific evidence. I disagree, however, with their implicit proposal that judicial acceptance be given to any re-analysis, done in any way the analyst wishes, and never reported in a disciplined scientific manner. If the work is worthy of attention as scientific evidence, it should be submitted to the scientific community for peer review and publication.

IV. META-ANALYSIS PRESENTS SPECIAL PROBLEMS IN ITS AGGREGATION OF DATA; IT IS VITAL THAT STANDARDS BE ESTABLISHED AND MET BEFORE SUCH DATA ARE PRESENTED TO A JURY.

The main statistical purpose of meta-analysis is to obtain statistical significance (or persuasive confidence intervals) for individual studies that did not originally achieve these mathematical accolades. They become achieved in the meta-analysis because the pooling of results for individual studies substantially increases the sample size of the aggregated results, and because significance testing and confidence intervals are so dependent on sample size.

From a scientific standpoint, however, meta-analysis is a highly controversial procedure because it combines heterogeneous entities into a single mixture. Apples, oranges, grapes and bananas may be pooled into a non-specific *fruit salad.* Fruit salad, garden salad, shrimp salad, and pasta salad may be pooled into a non-specific *salad.* Due to these inherent difficulties, scientific dispute has raged, and continues today, over the topic and methods of meta-analysis. *See, e.g.*, "Whither Meta-Analysis," *The Lancet*, April 18, 1987 at 897-898; K. Wachtler, "Disturbed by Meta-Analysis," Vol. 241, *Science*, September 16, 1988, at 1407-1408.

In general, there has been relatively broad but not complete agreement that meta-analyses are justified if the data come from randomized clinical trials. The randomization process can be relied upon (in general) to remove a biased assignment of treatment; and the trial itself will usually have been done with a careful protocol, planned in advance. There is no agreement, however, that meta-analyses are justified if the data come from epidemiologic or other studies that were done without the scientific safeguards of a randomized trial. It is possible, perhaps, to establish scientific standards for selecting reports, adjusting biases, and taking other precautions that might bring a modicum of scientific credibility to meta-analyses of epidemiologic data.[4]

I shall again agree, therefore, with the suggestion by Rothman, *et al.* that meta-analysis should not be automatically excluded from scientific or legal consideration. I shall once again disagree, however, with the laxity of their *laissez faire* permissiveness that would accept any meta-analysis, apparently done by anyone, without any specified standards for the procedure, using whatever "evidence"—published or unpublished—the analyst wants to include, and without any requirement that the analyst present the results to a scientific "jury" (through the process of publication) before they are unveiled in a courtroom. Meta-analysis, probably yes; without any specified scientific standards, surely no.

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[4] *See e.g.*, Z. Gerbarg and R. Horwitz, "Resolving Conflicting Clinical Trials: Guidelines for Meta-Analysis," 41 *Journal of Clinical Epidemiology* 503 (1987); H. Sacks, J. Berrier, D. Reitman, V. Ancona-Berk, and T. Chalmers, "Meta-Analyses of Randomized Controlled Trials," 316 *New England Journal of Medicine* 450 (1987).

V. CONFIDENCE INTERVALS, LIKE STATISTICAL SIGNIFICANCE, ARE A WAY OF MEASURING NUMERICAL STABILITY. EITHER TOOL MUST BE USED WITH ACCEPTED STANDARDS FOR RESULTS TO BE TRUSTWORTHY FOR EITHER SCIENTISTS OR JURIES.

In their principal argument, Rothman, *et al.* attack reliance upon statistical significance as being too arbitrary, and suggest the use of "confidence intervals" as an alternative. What is important to understand, however, is that both significance testing and confidence intervals are tools for evaluating the stability of the numbers being examined. In urging that significance testing be scientifically expunged and "removed from the inappropriate legal pedestal," Rothman, *et al.* completely ignore the necessity that the data used for drawing inferences be numerically stable, and that specific statistical standards must be established to demonstrate that stability. I shall offer some examples to illustrate the hazards posed by the abandonment of these standards.

A. Numerical Stability.

The numerical stability of quantitative information has been a prominent problem in medical science for at least 40 years. An investigator might claim that a new treatment, having a success rate of 75%, was substantially better than an older treatment, which had a success rate of 50%. Although the difference might initially seem impressive, the reader's enthusiasm might vanish with the discovery that the 75% rate represented only three successes in four patients, whereas the 50% success rate represented two successes in four patients.

These results are numerically unstable. If the next patient in each group fails with the new treatment, and succeeds with the old, the results in the two groups would be identical at 3/5 = 60%. On the other hand, if the original rates of 75% vs. 50% came from groups that each contained 400 patients, so that the comparison was

based on 300/400 vs. 200/400, the numerical results would be stable because the success rate of 75% vs. 50% would hardly be altered by whatever happened to the next patient in each group.

In the examples just cited, the instability of 3/4 vs. 2/4 and the stability of 300/400 vs. 200/400 are evident from visual inspection and a moment's thought. In many other instances, however, the conclusions are not so evident. For the success rates of 75% vs. 50%, stability would be much more difficult to evaluate if the numbers were 12/16 vs. 9/18, or 3/4 vs. 25/50.

B. Null Hypothesis and P Values.

To deal with these issues in numerical stability, scientists began using a statistical method that converted the challenge to an evaluation of probability. The evaluation proces begins with an assumption, called the *null hypothesis*, which postulates that the two treatments (or some other distinguishing feature of the two groups) are essentially identical. If the treatments are identical, and, if there is an observed difference of 75% vs. 50%, then that difference must have occurred by chance.

A mathematical mechanism, called a *P value*, was established to indicate the probability that the observed difference occurred by chance. If the chance probability seemed sufficiently remote, *i.e.*, P was small enough, the assumption that the two treatments were essentially identical would be regarded as untenable. Accordingly, the null hypothesis (with which the statistical reasoning began) would be rejected, and the results would be proclaimed "statistically significant". The implication of this conclusion was that the data were numerically stable, and that the observed difference was "real", *i.e.*, not due to chance.

C. Choice of Alpha Boundary.

To allow standard decisions during this analysis, a boundary level called α (alpha) was needed to separate

the sufficiently small probabilities from those that were "too big". According to recommendations made in 1925 by Sir Ronald Fisher, a giant in the pantheon of statistical methods, α was set at .05. R. Fisher, *Statistical Methods For Research Workers* (Edinburgh; Oliver & Boyd, 1925). After World War II, when medical journals and other evaluators of quantitative data began to concentrate on problems of numerical stability, they decided that any claims of important distinctions must be accompanied by "tests of statistical significance", and they accepted Fisher's boundary level of $\alpha = .05$. This decision was followed by the proliferation of statements in medical literature that "$P \leq .05$", *i.e.*, that in the published numerical results, if the two factors being compared were essentially identical, the probability that the observed distinction could have occurred merely by chance was less than 5%.

The quest for a "good" P value in research soon became so dominant that many readers and evaluators began to ignore the magnitude of the observed results themselves. Instead, if the P value showed "statistical significance", many readers inferred that the results were important and impressive. This inference was often wrong for two reasons: (1) the P value depended exclusively on the numerical data in the compared groups and had nothing to do with the scientific quality of the research design or the acquired evidence; and (2) the P value was immensely affected by the size of the groups (or "samples") under study.

To illustrate the first point, consider two baseball players with batting averages of .350 and .275, respectively. If each player has batted 500 times, so that the difference in batting averages is numerically stable, i.e., statistically significant, one might conclude that the first player was a better hitter than the second. This conclusion would be substantially undermined, however, by information that the second player played for the New York Yankees and the first player played for the Yankees of the Bridgeport,

Connecticut Little League. Statistical significance, standing alone, would be an inadequate basis to draw any scientifically appropriate inferences for the comparison of which player was the better hitter.

D. Role of Sample Size.

Similarly, a large enough sample is no guarantor of importance. If the sample is large enough, any difference, no matter how tiny or trivial, can become "statistically significant."[5] Continuing the baseball analogies, if two baseball players (in the same league) have lifetime batting averages of .283 vs. .284, the difference of .001 is essentially trivial in assessing their relative worth as hitters. Nevertheless, if each player has been to bat about 10,000 times, the difference will be "statistically significant" at $P < .05$.[6]

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[5] Another demonstration of this point can be made by briefly discussing how a P value is calculated. The discussion is important because the same calculation is used to construct a "confidence interval".

In the first step, a critical ratio, called Z, is formed by dividing the observed difference (such as 75%−50%=25%) by its "standard error".
Thus,

$$Z = \frac{\text{observed difference}}{\text{standard error}} \qquad [A]$$

The standard error is formed by dividing an entity called *standard deviation*, which represents variation in the data, by the square root of a factor that represents the *sample sizes* of the observed groups. Since standard error=(standard deviation)/(sample size factor), the formula for Z can be written as

$$Z = \frac{(\text{observed difference}) \times (\text{sample size factor})}{(\text{standard deviation})} \qquad [B]$$

After a level of α is selected, values of Z_α that correspond to α could be determined (from standard mathematical procedures). If the calculated value of Z (for the observed results) exceeds the chosen value of Z_α, the value of P would be $\leq \alpha$, and would be "statistically significant." Thus, the bigger the value of Z, the smaller would be the value of P, and, in symbols, if $Z \geq Z_\alpha$, then $P \leq \alpha$.

[6] The importance of sample size is evident on inspection of the foregoing formula [B] for Z. Since a big value is desired for Z to

When appraisers of statistical results began to focus on P values (such as $\leq .05$) rather than magnitude of the observed differences (such as .001), the role of science became neglected. Differences of important magnitude might be rejected as "non-significant" because the P value had the disastrous disadvantage of .051, whereas differences of unimportant magnitude might be accepted as "significant" because the P value had the impeccable virtue of .049. Consequently, many scientific writers (including myself) began publishing complaints about the rigidity of an α level of .05, and its concomitant distraction from concentration on the scientific quality of the research.

The complaints did not urge that standards of numerical stability be abandoned. Almost all thoughtful scientists would agree that such standards are necessary, and that $\alpha = .05$ is a reasonable general standard. The argument was mainly that the α level should be somewhat flexible (for situations beyond the scope of the discourse here) and that mathematical P values should not replace the evaluation of the *scientific* quality of the evidence. In their battle against significance testing, Rothman, *et al.* do not at all address the important issues of either numerical stability or scientific quality.

E. Calculation of Confidence Intervals.

Rothman, *et al.* urge a judicial preference for confidence intervals over P values but do not explain why such a preference is needed or justified.

A confidence interval is a way of examining the possible range of a relative risk or other numerical distinction between two studied groups. The interval offers an estimate of the range for the "true" value of the

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exceed Z_α, and since the sample size factor multiplies the quotient of (observed difference)/(standard deviation), a large enough sample size factor will convert any observed difference into a product large enough to exceed Z_α.

distinction. The interval cannot be constructed without choosing a level for α, and the interval is demarcated with $1 - \alpha$. Thus, if $\alpha = .05$, $1 - \alpha = .95$ and the interval is called a 95% confidence level interval. With a 95% confidence level interval, there is a chance of only 5% that the possible actual distinction between the two studied groups falls outside the range.

The confidence level is an inverse counterpart of decisions with a P value, because both depend on the level chosen for α. The choice of α determines the value of $1 - \alpha$ that is associated with the confidence level. Thus, if $\alpha = .05$, then $1 - \alpha = .95$, and the designation is 95% confidence level. If $\alpha = .1$ or $\alpha = .01$, then the respective designations are 90% confidence interval or 99% confidence interval. Consequently, confidence intervals are an alternative mathematical approach to the probabilistic evaluation of numerical stability. The mathematical reasoning and data are identical with either approach.[7]

Unlike the solitary result of the P value, however, a confidence interval has two values, an upper and lower end of the interval. The lower end produces exactly the same decision as the calculation of a P value. The upper value, however, provides additional information, suggesting how much larger the true difference might have been than what was observed. For this reason, the confidence interval is particularly valuable when an investigator,

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[7] In the foregoing formula [A] for the calculation of Z, the requirement for statistical significance is that

$$\text{(observed difference)/(standard error)} \geq Z_\alpha \qquad [C]$$

Formula [C] can be rearranged algebraically to show that the requirement for statistical significance is

$$\text{(observed difference)} - (Z_\alpha)\ \text{(standard error)} \geq 0 \qquad [D]$$

Expressed in mathematical terms, the "null hypothesis" value of 0, *i.e.*, no difference in the two treatments, should be excluded from the zone formed in Formula [D] when the product, (Z_α) (standard error), is subtracted from the observed difference. This is the same Z_α used earlier for the decision with formulas [A] or [B].

having found a small observed difference, is tempted to conclude that it is insignificant. In this situation, if the confidence interval is too wide, the investigator cannot conclude there is no difference. For such a situation, further investigation is warranted. In the more customary situation, however, where the investigator finds an impressive difference and wants to claim that the difference is statistically significant, the P value and the confidence interval techniques yield the same conclusion. Because of the added bonus offered by confidence intervals, many investigators (and evaluators) have begun to prefer confidence intervals over P values, although the primacy of the P value is still supported by many prominent statisticians.

The use of confidence intervals, however, does not in any way eliminate the necessity for numerical standards. The most common and widely accepted standard is the use of a 95% confidence interval, which is precisely analogous to a P value of .05, which denotes "statistical significance." The critical issue is what level of α is to be acceptable for scientists in the scientific arena, and for jurors in the legal arena. The choice of α must be made whether statistical significance or confidence intervals are used.

In their argument that confidence intervals should be judicially preferred over the P values of "significance testing," Rothman, *et al.* do not refer to the importance of adherence to accepted standards in selecting the boundary level to measure the stability of numbers. In fact, Rothman, *et al.* mention no standards, no boundaries, and nothing about the importance of a level for α, although such a level must be chosen to allow a confidence interval to be calculated. With no constraints on levels of α, data analysts would apparently be free to choose these levels in any way they want. The choice of α (or $1-\alpha$) can make the confidence intervals as large or as small as the investigator wishes, and can thus make the data support whatever results the data analyst would like to demonstrate.

Thus, Rothman, *et al.* are apparently urging that the occasionally excessive rigidity of P values be replaced by the anarchy of unrestricted confidence intervals. Whatever the statistical impact of this change, of course, neither the P value nor the confidence interval addresses the fundamental scientific necessity of quality in the research design and data.

Rothman, *et al.* suggest that their position on numerical stability is supported by "a large community of respected epidemiologists." Rothman Brief at 8. If so, I suspect that the epidemiologists do not really understand precisely what is implied in Rothman, *et al.*'s recommendations. I feel certain that most members of the "community" of scientists would reject the numerical anarchy that is being proposed. They would insist that standards of intellectual discipline be honored, that standards of numerical stability be maintained, and that evidence not be accepted if it fails to meet the standards of numerical stability. The standards can be established either via P values or circumscribed confidence intervals (or even with some new "fragility" techniques that are beyond the scope of this discussion). The standards should be appropriately flexible, but they must exist if science is to preserve its tradition of intellectual discipline and high quality research.

I can think of no better way to allow "junk science" into both the published literature and the courtroom than to remove the constraints that demand numerical stability for data. If researchers can choose confidence intervals in an *ad hoc* manner, without justifying their selection of appropriate boundary values according to accepted scientific standards, the result will be confidence games, not confidence intervals.

CONCLUSION

Standards and peer review, especially as reflected in published scientific work, are vital to the understanding of practicing scientists in their own work. Such requirements are equally important if scientific information is to be used when juries make decisions. If scientific and statistical standards are abandoned, and if juries receive untrustworthy information, courtroom decisions will be based on unfettered speculation and conjecture.

Respectfully submitted,

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APPENDIX

IDENTIFICATION OF AMICUS CURIAE

Alvan R. Feinstein was born in Philadelphia in 1925. He received his Bachelor of Science degree, a Master's Degree in Mathematics, and his Doctor of Medicine degree from the University of Chicago. After residency training in internal medicine at Yale University and at Columbia-Presbyterian Hospital in New York, and after a research fellowship at the Rockefeller Institute, he became medical director at Irvington House, just outside of New York City, where he studied a large population of patients with rheumatic fever. In this research, he began developing new clinical investigative techniques that were eventually expanded beyond rheumatic fever into many other activities, particularly work on the prognosis and therapy of cancer.

His new clinical epidemiologic approaches and methods were first reported in two books, *Clinical Judgment* (Williams & Wilkins Co., 1967, Reprinted, Robert E. Krieger Publishing Co., 1974) and *Clinical Biostatistics* (C.V. Mosby Co., 1977). His two latest books, *Clinical Epidemiology* (W.B. Saunders Co., 1985) and *Clinimetrics* (Yale University Press, 1987), describe the structure and contents of clinical research with groups, and the strategy used to form clinical indexes and rating scales for important human clinical phenomena—such as pain, distress, and disability—that have not received adequate attention in an age of technologic data.

To supplement the current biomedical forms of "basic science" that are used for explanatory decisions about pathophysiologic mechanisms of disease, Dr. Feinstein has vigorously advocated that clinical epidemiology and clinimetrics be developed as an additional humanistic "basic science" for the managerial decisions of clinical practice.

Dr. Feinstein was instrumental in pioneering the field of clinical epidemiology. He has cautioned against overreliance on statistical results and stressed the need for attention to the descriptive data that are the foundation of clinical therapy and to basic scientific principles in the collection and analysis of data. From 1970 to 1974, Dr. Feinstein served on the Biomedical Epidemiological Methodology Advisory Committee of the Food and Drug Administration. Since that time, Dr. Feinstein has continued to advocate the development of a well delineated set of scientific standards, based on rigorous application of accepted scientific principles, for conducting epidemiologic investigations.

Dr. Feinstein is Sterling Professor of Medicine and Epidemiology at the Yale University School of Medicine, where he is also Director of the Clinical Epidemiology Unit, the Robert Wood Johnson Clinical Scholars Program, and the Introduction to Clinical Medicine Course (for second-year medical students). He has held numerous visiting professorships at universities in this country and abroad, and he served a six-year term (1977-1983) as a member of the governing board of the American Board of Internal Medicine. He has been elected to the American Epidemiological Society and to the Association of American Physicians, being one of a few medical academicians chosen for both of these prestigious groups.

Dr. Feinstein has been awarded many honors for his work in the fields of medicine and public health. These honors include the Richard and Hinda Rosenthal Foundation Award from the American College of Physicians in 1982 for "making a notable contribution to improve clinical care in the field of internal medicine"; the Robert J. Glaser Annual Award of The Society for Research and Education in Primary Care Internal Medicine in 1987 for "exceptional contributions to research and education in the field of general internal medicine"; and the J. Allyn Taylor International Prize in Medicine in 1987, for "sig-

nificant contributions to a field of basic or clinical research" (shared with Peter Armitage and David L. Sackett).

Dr. Feinstein has served on the editorial boards of many medical and scientific journals, including the *Journal of Chronic Diseases*, the *Archives of Internal Medicine*, the *Journal of the American Medical Association*, *The Statistician*, and *Clinical Pharmacology and Therapeutics*. He is past editor of the *Journal of Chronic Diseases* and is currently co-editor of the *Journal of Clinical Epidemiology*.

Dr. Feinstein has written or co-authored more than 300 articles that have appeared in the medical and scientific literature during the last 40 years.

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IN THE
Supreme Court of the United States

October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, INDIVIDUALLY AND AS GUARDIANS AD LITEM FOR JASON DAUBERT, AND ANITA DE YOUNG, INDIVIDUALLY AND AS GUARDIAN AD LITEM FOR ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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QUESTIONS PRESENTED

1. Whether, in light of the Federal Rules of Evidence, federal courts may apply the rule of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), and hold expert scientific testimony inadmissible unless it has attained general acceptance in the relevant scientific field.

2. Whether the *Frye* rule (assuming its applicability) is properly construed to make the admissibility of expert scientific testimony depend upon prior publication in a peer-reviewed journal.

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Ninth Circuit is reported at 951 F.2d 1128, and is reprinted at J.A. 237.[1] The memorandum decision and order of the United States District Court for the Southern District of California is reported at 727 F. Supp. 570, and is reprinted at J.A.227.

JURISDICTION

The decision of the Court of Appeals was entered on December 20, 1991. A timely petition for rehearing was denied on April 8, 1992. See J.A. 242. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1). A timely Petition for Writ of Certiorari was granted by the Court on October 13, 1992.

STATUTORY AND CONSTITUTIONAL PROVISIONS

The Federal Rules of Evidence were enacted by Congress in 1975, Pub. L. No. 93-595, 88 Stat. 1926 (1975), 28 U.S.C. app. (1988). Set forth at App. 1-6 to this Brief are the complete text of Rules 104(a) & (b), 401 to 403, 501, 602, 701 to 706, 803(18), 803(24), and 804(b)(5). The complete Advisory Committee's Notes to the Rules and other pertinent legislative history may be found in *Federal Rules of Evidence for the United States Courts and Magistrates* (West Publishing Co. 1992). Set forth at App. 7 are 28 U.S.C. §§ 2071 and 2072, as well as the Rules Enabling Act, 28 U.S.C. § 1652.

STATEMENT OF THE CASE

Petitioners Jason Daubert and Eric Schuller are minor children born with severe and permanent limb-reduction birth defects. They and their parents ("plaintiffs") brought suits for damages in California state court against respondent, Merrell Dow Pharmaceuticals, Inc. ("Merrell"), alleging that the birth defects had been caused by the mothers' ingestion of Bendectin, a prescription anti-nausea drug marketed by Merrell. The complaints alleged exclusively state law causes of action: strict liability, negligence and breach of warranty.

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[1] Page citations to the Joint Appendix will be styled "J.A.___." Page citations to the Appendix to this Brief will be styled "App. ___."

Merrell removed the lawsuits to federal district court on the basis of diversity of citizenship. Merrell then answered the complaints, denying *inter alia* that the minor plaintiffs' birth defects had been caused by Bendectin. The cases were consolidated for all purposes pursuant to Fed. R. Civ. P. 42.

A. The Summary Judgment Record

After extensive discovery, Merrell moved for summary judgment. Merrell's motion did not contest that the mothers of the minor plaintiffs ingested Bendectin during the critical period of pregnancy in which the limbs of their children were formed. Nor did Merrell's motion suggest that these children had been exposed to any other substances capable of causing limb reductions, or that there were any genetic factors in the family backgrounds that might account for the limb defects.

Rather, the sole ground of the motion was Merrell's claim that "plaintiffs . . . can offer no admissible evidence that proves" that Bendectin causes birth defects.[2] In support of its motion, Merrell submitted an affidavit, two pages in length, of Stephen H. Lamm, a physician and epidemiologist who is President of Consultants in Epidemiology and Occupational Health, Inc.[3] In the affidavit, Dr. Lamm recited that he had reviewed all of the literature on Bendectin and human birth defects. Based upon that literature, and upon his observation that there has been no correlation between "the annual frequency of Bendectin usage and the annual occurrences of specific birth defects," Dr. Lamm concluded "that maternal use of Bendectin during the first trimester in pregnancy is not a risk factor for human birth defects in general, for limb reduction defects specifically, or for any other particular human birth defect." (J.A. 32-33).

Plaintiffs responded to the summary judgment motion by submitting testimony of eight expert witnesses skilled in several relevant scientific and medical disciplines, all of whom disagreed

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[2] Defendant's Memorandum of Points and Authorities in Support of its Motion for Summary Judgment on the Issue of Causation, at 2.

[3] J.A. 32-33. The affidavit was accompanied by a several-page curriculum vitae of Dr. Lamm establishing his credentials to offer expert opinion testimony on the issue of causation. J.A. 34-44.

with Dr. Lamm's conclusion and reasoning.[4] In addition, plaintiffs submitted six volumes of exhibits, containing trial and deposition testimony of other experts in other cases together with documentary material supportive of their experts' testimony (such as excerpts from scientific text books on teratology and epidemiology).

The experts whose opinions plaintiffs proffered have outstanding credentials, and hold important positions in their fields.[5] These

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[4] Affidavits were submitted from six of the expert witnesses (J.A. 53-60, 61-66, 73-80, 112-17, 148-53, 187-92), supplemented in the case of four by testimony they had given in other Bendectin cases (Attachment to Daubert/Schuller Opposition to Summary Judgment, Tabs 12 (Swan), 21 (Newman), 26 (Gross), 32 (Glasser)). [Throughout this brief, citations to the materials compiled in the attachment to the summary judgment opposition will be cited simply as "Tab __"] The opinions of the other two experts were proffered via transcripts of their testimony in other cases (Tabs 20 (Snodgrass), 31 (Done)).

[5] Shanna Swan, who received a masters in biostatistics from Columbia and a PhD in statistics from the University of California at Berkeley, is chief of the section of the California Department of Health and Services that determines causes of birth defects. Dr. Swan has also served as a consultant to the World Health Organization, the Food and Drug Administration and the National Institute of Health. J.A. 113-14, 131-32.

Jay Glasser, who received a masters in biostatistics at Columbia and a Ph.D. in experimental statistics at North Carolina State, is a professor of epidemiology at the University of Texas and is serving as court-appointed expert on causation issues in the Dalkon Shield litigation. J.A. 148-49.

Adrian Gross, DVM, a veterinary pathologist, has been employed continuously since 1964 by the Food and Drug Administration and the Environmental Protection Agency in such positions as Chief of Pharmacology at the FDA and Chief of Toxicology at the EPA (in both agencies his responsibility involving determination whether drugs and chemicals cause toxic effects); currently, he is Senior Science Advisor to the EPA and is also consulted by the FDA on causation issues. J.A. 74-76, 85-89; Tab 26 at 850-52.

Stewart Newman, who received his masters and Ph.D. in chemistry from Columbia and the University of Chicago respectively, is a professor at New York Medical College and has devoted more than 15 years to research on the effect of chemicals upon limb development. J.A. 54-56; Tab 21, pp. 186, 196-201. Dr. Newman's work was featured in a *Newsweek* cover story in 1982 describing embryology as the frontier area in biological research. Id.; Tab 35 (Newman) at 370.

See also J.A. 62-63 (Frederick Crescitelli); J.A. 188-90 (John Palmer); Tab 18 (curriculum vitae) and Tab 20 at 2 (Wayne Snodgrass); Tab 18 (curriculum vitae of Allan Done).

experts all concluded that Bendectin[6] is a human teratogen (i.e., a substance capable of causing malformations in human fetuses), and that when ingested at the normal therapeutic dose during the period of pregnancy in which limbs are forming, Bendectin is capable of producing limb defects in human fetuses.[7] Dr. Palmer further concluded that, taking account of Bendectin's teratogenic properties respecting human limbs, the timing of its ingestion by the mothers of the two minor plaintiffs (i.e., during the period of limb formation in the fetus), and the absence in their medical records of any other factor that might explain the birth defects, Bendectin was in fact the cause of the limb reductions suffered by the minor plaintiffs in this case.[8]

In explaining the bases for these conclusions, the experts' affidavits (corroborated by the other materials submitted by plaintiffs in opposition to the summary judgment motion) establish the following subsidiary propositions.

1. The Types of Data Relied Upon By Plaintiffs' Experts and By Scientists Generally in Forming Conclusions as to Whether Human Birth Defects Are Caused by a Suspected Toxin

The experts based their conclusions respecting causation upon an analysis of four sources of information:

(a) "in vivo" animal studies (comparing the offspring of animals subjected to dosages of Bendectin during pregnancy with the offspring of those not subjected to Bendectin);

(b) "in vitro" studies (microscopic examination of animal cells exposed to Bendectin, to determine whether abnormal cell development associated with human limb birth defects results);

(c) pharmacological studies, which examine the chemical structure of Bendectin (and, particularly, of its antihistaminic

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[6] In some instances, the expert opinion was more precise, identifying the teratogenic agent as the antihistaminic component of Bendectin, called doxylamine succinate.

[7] J.A. 56-60, 63-65, 77-80, 116-17, 152, 191-92; Snodgrass, Tab 20, at 82.

[8] J.A. 192.

component) and compare that structure with the structures of other similar substances known to cause comparable birth defects in humans; and

(d) epidemiological studies (data gathered in studies comparing the incidence of birth defects of various types in the offspring of women who took Bendectin during pregnancy with those of women who did not).

The experts' affidavits submitted by plaintiffs recite that these four sources of information are the standard sources consulted by scientists generally when attempting to form opinions about whether a substance is causing birth defects.[9] Plaintiffs also submitted, in their opposition to the summary judgment motion, the testimony of numerous experts *called by Merrell* in other litigation, agreeing that conclusions respecting causation are customarily predicated upon the results of all four of these sources (and not merely upon the results of epidemiological studies).[10] For example, Merrell's Vice President of Drug Safety Assessment, himself a veterinary pathologist, has testified that the reason Merrell does animal studies is so that "from the data derived [therefrom]" scientists can "make a judgment of predictive value in human beings." (J.A. 109, 111). Even Dr. Lamm, the author of the sole affidavit submitted by Merrell below, has testified elsewhere that all four sources (and not merely epidemiological data) are helpful in determining whether Bendectin causes human birth defects. (J.A. 46-47). The Food and Drug Administration and the Environmental Protection Agency rely upon all four sources in determining causation,[11] and a study published by the congressional Office of Technology Assessment explains why it is "necessary" to consult these sources and not rely solely on epidemiological data.[12]

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[9] J.A. 56-60, 76-79, 115-17, 191; Tab 20, p. 14; Done, Tab 31, p. 565.

[10] Jones, Tab 7, p. 2664; Seltzer, Tab 11, pp. 2553-54; Luthy, Tab 15, p.30; Shepard, Tab 17, pp. 3645-46; Skalko, Tab 29, pp. 28-29; Scott, Tab 30, p. 1988; and see sources cited next in text.

[11] J.A. 106-07; Gross, Tab 26, pp. 817-18, 847-49; Jones, Tab 7, p. 2664.

[12] J.A. 209.

The scientific discipline that employs these four data sources is known as teratology — the study of non-genetic causes of birth defects.[13] It became important as a field after the Thalidomide experience of 1961, which exploded the assumptions, until then widely shared by biologists and doctors, that all birth defects were genetically determined and that substances ingested by the mother could not harm the fetus because "the mammalian embryo developed within the virtually impervious shelter of the uterus and the maternal body where it was protected from extrinsic factors."[14] Scientists now realized that some substances could pass through the placenta and reach the developing fetus.[15] Although more has been learned since 1961, the field remains one in which scientific advances continue to be made.[16]

2. The Experts' Conclusions Based Upon That Data

In the instant case, plaintiffs' experts concluded, from the following data considered collectively, that there is a causal link between Bendectin and human limb reduction birth defects.

(a) In vivo animal studies have demonstrated overwhelmingly that Bendectin causes limb reductions and other birth defects in a variety of animals that have been tested.[17] In general, animal studies such as these have "good predictive value for humans."[18]

(b) In vitro animal studies have confirmed that Bendectin causes damage and destruction of the cells that are responsible for limb

[13] Tab 21, p. 210 (Newman).

[14] Tab 6, J. Wilson, "Current Status of Teratology,'" in 1 *Handbook of Teratology* 47 (Tab 6, p.47).

[15] J.A. 63.

[16] Wilson, supra, Tab 6, at 49, 60; A. Mitchell, D. Slone, S. Shapiro & P. Goldman, "Adverse Drug Effects and Drug Surveillance", in Yaffe, *Pediatric Pharmacology*, Tab 8, p. 65 [hereinafter, Yaffe Tab 8].

[17] J.A. 76-79; Gross, Tab 26 at 720-22, 796-802, 807-11, 829-34. Indeed, a federal agency has identified Bendectin as a "developmental toxicant" (i.e., a teratogen) in animals. Gross, Tab 26, at 900-04.

[18] J.A. 209 (Office of Technology Assessment report).

formation in the fetus, another predictor of risk for humans.[19]

(c) Chemical structure analyses reveal that the antihistaminic component of Bendectin is similar in structure to that of other antihistamines known to cause limb reduction birth defects when ingested at the critical stage of fetal limb formation.[20]

(d) Epidemiological studies performed on humans prior to Bendectin's withdrawal from the market in 1983 showed a higher incidence of limb reductions in babies born of Bendectin-using mothers than in other babies,[21] although the epidemiologists who had conducted those studies had regarded the results as inconclusive because they fell short of proving an association between Bendectin and limb reductions to the 95% confidence level those epidemiologists had chosen as the measure of "statistical significance."[22]

(e) The epidemiologists conducting those studies had found statistically significant associations (at the 95% confidence level) between Bendectin and three other human birth defects,[23] and as teratogens that damage developing cells tend to leave multiple abnormalities,[24] these findings strengthen the inference to be drawn from the raw data indicating a link to limb reduction as well.[25]

[19] J.A. 57-59; Newman, Tab 21, pp. 258-94.

[20] Newman, Tab 21, pp. 233-58. It is a "basic precept of biology" that organisms are most susceptible to change while they are in the formative stage, and this is especially true of change in the form of growth retardation. The "critical period" is the period of pregnancy when the organ in question is forming. Wilson, Tab 6 at 50-52, 58. In the case of human limbs, the critical period is the fourth to eighth week following conception. Newman, Tab 21 at 214-27.

[21] J.A. 151-52; Glasser, Tab 32 at 132-41, 145-48.

[22] As explained *infra*, pp. 9-10, n.33, limb reduction is a very uncommon occurrence, and as a result studies will not yield statistical significance at the 95% confidence level unless populations larger than those in the Bendectin studies are followed.

[23] Glasser, Tab 32 at 104-14.

[24] Gross, Tab 26 at 768.

[25] Glass, Tab 32, at 133-34.

3. The Areas of Scientific Disagreement

The crux of the disagreement between Merrell's experts and those whose testimony is put forward by plaintiffs is that the latter are prepared to find causation more probable than not when the epidemiological evidence is strongly positive (albeit not at a 95% confidence level) and when it is buttressed with animal and chemical evidence predictive of causation, while the former are unwilling to find causation in the absence of an epidemiological study that satisfies the 95% confidence level. Merrell's position, articulated in its reply to plaintiffs' opposition to the summary judgment motion, was that evidence of causation is inadmissible unless it includes a "published epidemiological study performed on Bendectin which shows a statistically significant causal association between Bendectin and the incidence of limb reduction defects in humans."[26]

At the root of the disagreement between the experts proffered by plaintiffs and by Merrell are two hotly-disputed points. The first relates to the degree of confidence that should be demanded of epidemiological studies before concluding that there is causation in the torts context; the second relates to the integration of epidemiological evidence with the animal/chemical "hard science" evidence.

(a) Statistical experiments assume a "null hypothesis" (i.e. that the factor under study is not a cause of the results to be observed) and then ask whether the observable data depart from that hypothesis. In a study of a chemical's propensity, for example, there will be two groups studied, one that ingested the chemical and one that did not. If the null hypothesis is true (i.e. the chemical does not cause human defects) the two groups should show no difference in the incidence of defects.[27] But, of course, even when the null hypothesis is true, in nature there are random events that will skew the data. Accordingly, scientists are cautious about drawing conclusions respecting causation simply because the observable data show some variation from the null hypothesis.

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[26] Defendant's Reply to Plaintiffs' Opposition to Defendant's Motion for Summary Judgment, p. 2.

[27] K. Rothman, *Modern Epidemiology* (Tab 9), at pp. 116-17.

In their quest for certainty, scientists have conventionally insisted upon a very high threshold of confidence before being willing to declare truths from statistical evidence; in the absence of that degree of confidence, scientists prefer to declare the results inconclusive and continue their search. To this end, an "arbitrary point . . . is selected," usually one that requires 95% confidence that the skew is not the result of randomness.[28] Under this approach, a statistical result is not deemed "significant" unless the data are such that there is less than one chance in twenty that the data would skew so far and yet the null hypothesis still be true. In this manner, the risk of "Type I" error — the risk that a false-positive correlation will be found (here, of causation) — is kept below 5%.[29]

But in toxic tort lawsuits, the issue is not whether it is certain that a chemical caused a result, but rather whether it is "likelier than not" that it did. It is not self-evident that the latter conclusion would require eliminating the null hypothesis (i.e. non-causation) to a confidence level of 95%.[30] And, indeed, to insist upon such a high level of confidence is to risk a much greater error in the other direction — a "Type II" or "false-negative" error: that causation will not be found although in fact it is occurring.[31] Dr. Swan calculated the risk of Type II error from the Bendectin studies and found, as to each study, that *even if Bendectin were causing a doubling of the incidence of human limb reductions* there was less

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[28] Rothman, supra, Tab 9 at 116.

[29] Yaffe, Tab 8, at p. 68; Rothman, Tab 9, at pp. 115-17. Of course, as these textbooks emphasize, the fact that statistical data fall short of showing an association at the 95% level is not evidence that proves the *absence* of causation. Yaffe, Tab 8 at 69; Rothman, Tab 9 at 116-17. *A fortiori*, it cannot be evidence of non-causation when, as here, the data show a positive correlation.

[30] This is a point that many scientists have been attempting to communicate to lawyers, most recently in an article that explains the error in dismissing the epidemiological evidence respecting Bendectin as non-probative. V. Brannigan, V. Bier, and C. Berg, "Risk, Statistical Inference, and the Law of Evidence: The Use of Epidemiological Data in Toxic Tort Cases, 12 Risk Analysis 343 (1992). See also, Rothman, Tab 9, at 117-18 (criticizing the importance attached to significance at the 95% confidence level.)

[31] Yaffe, Tab 8, at p. 69; Rothman, Tab 9, at pp. 117-18.

than a 20% chance that the study would yield a "statistically significant" outcome if "significance" was defined as confidence at the 95% level.[32] This is because epidemiological studies are unlikely to detect (at a 95% confidence level) adverse reactions, such as limb reduction, that are experienced by only a small percentage of the population.[33] In other words, to require a 95% confidence showing would be to protect against a 5% risk of erroneously finding causation when it is not present, *while creating a greater than 80% risk that true causation doubling the incidence of harm would go undetected.*

The epidemiological studies of Bendectin showed a higher relative incidence of birth defects among the offspring of mothers who ingested Bendectin than among those who did not.[34] But the populations covered in the studies were not large enough to allow a finding of causation with the level of "statistical significance" set at 95%.[35] The data would, however, allow a finding that causation is far likelier than not, albeit at confidence levels somewhat below 95%.[36]

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[32] Swan, Tab 12, at pp. 3578, 3597-98.

[33] Yaffe, Tab 8, at 65, 69, 71-72 (even adverse reactions affecting 1 in 100 of those tested are not likely to yield statistical significance at a 95% confidence level); Swan, J.A. 116; Tab 12 at 3568 (limb reductions affect less than 1 in 1,000); Glasser, Tab 32 at 30-32, 77-80.

[34] *See* p. 7, *supra*. Statisticians define the "relative risk" as the rate of occurrence in the exposed group (here, mothers taking Bendectin at the critical period) divided by the rate of occurrence in the nonexposed group. Yaffe, Tab 8, at 68. If 2% of the users of the substance being studied give birth to children with birth defects, but only 1% of those not using the substance, the relative risk would be 2.0 (2% divided by 1%).

[35] Swan, Tab 12 at 3600; Glasser, Tab 32 at 134-41, 145-48. *See also* p. 10 n.33, *supra*.

[36] An alternative mechanism has been developed by epidemiologists in recent years to give a somewhat more informative picture of what the statistics mean. At any given confidence level (e.g. 95%) a "confidence interval" can be constructed. The confidence interval identifies the range of relative risks that collectively comprise the 95% universe. Additional confidence levels are then constructed exhibiting the range at other confidence levels, e.g., at 90%, 80%, etc. From this set of "nested confidence intervals" the epidemiologist can make assessments of how

(b) The second source of dispute among experts relates to the integration of epidemiological data with the animal and chemical data. Some experts, while acknowledging that animal and chemical studies can point in the direction of causation, are unwilling on that account to reduce the confidence level required of epidemiological evidence before it will convince them of causation. Plaintiffs' experts, by contrast, have testified that it is appropriate to consider the combined weight of the animal, chemical and epidemiological evidence, and to accept epidemiological evidence as indicative of causation at a lower confidence level when it is buttressed by animal and chemical evidence strongly suggesting causation.

Plaintiffs' experts testified that this latter approach is particularly appropriate when, as they explained was the case here, the epidemiological studies (whether because of methodological flaws[37] or insufficient sample size[38]) were unlikely to detect a positive association of the drug with birth defects even if the association

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likely it is that the statistics are showing a true association. Rothman, Tab 9, pp. 122-25. By calculating nested confidence intervals for the data in the Bendectin studies, Dr. Swan was able to determine that it is far more likely than not that a true association exists between Bendectin and human limb reduction birth defects. Swan, Tab 12, at 3618-28.

[37] Dr. Swan testified at length describing the methodological flaws in the Bendectin studies that were conducted prior to its removal from the market, virtually all of which had the effect of *understating* the degree of association between Bendectin users and limb reduction birth defects. Swan, Tab 12, at 3600-18, 3649-55. Among the flaws she described were, e.g., lumping limb reductions together with other limb defects in the reporting (since limb reductions occur only one-tenth as often as other limb defects, the effect was to dwarf entirely the ability to detect the association relevant to this case); including women who first ingested Bendectin after their eighth week of pregnancy in the Bendectin-user group, rather than the control group (since the limbs of the fetus are formed after eight weeks, Bendectin could no longer harm them; including them on the wrong side of the equation skewed both numbers against association); including in the control group mothers taking other antihistamines (since some antihistamines are known to cause limb reduction birth defects, the effect was to increase the risk of birth defects on the non-Bendectin side of the equation, but on grounds that do not rule out the toxic effect of Bendectin). *Id*. See also Glasser, Tab 32 at 119-26, 129.

[38] Swan, Tab 12, at 3600. *See also* p. 10 n.33, *supra*.

existed.[39]

B. The District Court's Opinion

On the basis of the record just described, the district court granted summary judgment to Merrell and dismissed the complaints. The court explained that it "should exclude inadmissible evidence objected to by either party prior to ruling upon the motion." (J.A. 229). From that unassailable starting point, the court leapt to the more controversial one that is the focus of the issue before this court: "A necessary predicate to the admission of scientific evidence is that the principle upon which it is based 'must be sufficiently established to have general acceptance in the field to which it belongs.'" (*id.*, citing *United States v. Kilgus*, 571 F.2d 508, 510 (9th Cir. 1978)). Although the district court did not cite the *Frye* case, this is the *Frye* rule.[40]

The court then proceeded to apply that rule to this case. While there are "two schools of thought governing expert testimony in these Bendectin cases," the school that "seems to be prevailing in the federal courts" is that "causation may be shown only through reliance upon epidemiological evidence." (J.A. 229-30). What is more, only epidemiological evidence that is "statistically significant" may be used to prove causation. (J.A. 235). The experts' testimony proffered by plaintiffs did not, in the district court's view, meet this profile.[41] Accordingly, summary judgment was granted in favor of defendants on all causes of action. (Pet. J.A. 236).

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[39] Their position on this point is bolstered by the report of the congressional Office of Technology Assessment, confirming the difficulties of securing meaningful results from epidemiological data and citing those difficulties as a reason why animal studies are "necessary." J.A. 209.

[40] While the district court did not cite *Frye*, the *Kilgus* opinion from which it quoted the rule cited *Frye* as its source. The district court apparently believed that the *Frye* rule is dictated by Rule 703 of the Federal Rules of Evidence (J.A. 229), although *Kilgus* did not mention the Federal Rules of Evidence and appears to have assumed that the *Frye* rule exists independently of the Federal Rules of Evidence. In the argument, petitioners address both whether the *Frye* rule can stand independently and, if not, whether it is a proper interpretation of Rule 703.

[41] The district court did not explain what it believed constituted statistical significance, but a review of the cases it cited indicates that it understood the term to require a showing that satisfied the 95% confidence level.

C. The Court of Appeals' Opinion

The court of appeals agreed that the testimony of the experts proffered by plaintiffs was inadmissible. "Expert opinion based on a scientific technique 'is admissible if it is generally accepted as a reliable technique among the scientific community'" (J.A. 238 (citing *Frye*)) Whether expert testimony satisfies this requirement "is reviewed *de novo* by [the] appellate court," because "the reliability of a scientific technique or process does not vary according to the circumstances of each case" and thus cannot appropriately be left "within each trial judge's individual discretion." (J.A. 238-39).

"For expert opinion based on a given scientific methodology to be admissible, the methodology cannot diverge significantly from the procedures accepted by recognized authorities in the field." (J.A. 239). The court explained that expert testimony of causation will not be admissible if it is not supported by epidemiological studies. (J.A. 239-40). Although plaintiffs' experts rested their conclusions in part upon a reanalysis of epidemiological studies, the court held that "reanalysis of epidemiological studies is generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field." (J.A. 240). "Plaintiffs' reanalyses do not comply with this standard; they were unpublished, not subjected to the normal peer review process, and generated solely for use in litigation." (J.A. 240-41). The court concluded:

> [W]e agree with the district court that the available animal and chemical studies, together with plaintiffs' expert reanalysis of epidemiological studies, provide insufficient foundation to allow admission of expert testimony to the effect that Bendectin caused plaintiffs' injuries. Accordingly, plaintiffs could not satisfy their burden of proving causation at trial . . . . "When the contested evidence is essential to the cause of action and the trial court has excluded the evidence, we may decide the appeal . . . solely on the basis of the soundness of the evidentiary ruling. For if we uphold the exclusion of essential evidence, the [review of the summary judgment ruling] becomes academic."

J.A. 241 (brackets in opinion).[42]

On October 13, 1992, this Court granted certiorari. 113 S. Ct. 320 (1992).

SUMMARY OF THE ARGUMENT

The central issue in this case is whether the rule of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) — that expert scientific opinion evidence is inadmissible unless it has attained general acceptance in the relevant scientific field — survived the enactment of the Federal Rules of Evidence in 1975.

1. *Frye* cannot stand as a judge-made rule of evidence independent of the Federal Rules. Rule 402 declares that "all relevant evidence is admissible except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority." The failure to list judge-made rules in the exception is conspicuous, and it was not inadvertent. Congress wanted to broaden the admissibility of evidence, and to that end it "wiped the slate clean" with Rule 402 and then adopted expressly those of the common-law rules for excluding evidence that it wished to retain. In the one instance where Congress decided to leave room for further judicial elaboration of exclusionary rules — the area of privileges — Congress expressly so provided (see Rule 501).

2. Thus *Frye* survives only if it was incorporated into the Federal Rules in 1975. But there is not a word in the Rules as enacted, nor in the Advisory Committee's Notes or legislative history, suggesting that Congress adopted *Frye* (or any other "general acceptance" requirement for expert testimony) as an exception to Rule 402's broad declaration of admissibility.

This is not surprising, for the Rules follow the "general approach of relaxing the traditional barriers to 'opinion' testimony." *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988), and *Frye* had been widely condemned by leading evidence commentators

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[42] Quoting from *Christophersen v. Allied-Signal Corp.*, 939 F. 2d 1106, 1109 (5th Cir.) (en banc), *cert. denied*, 112 S. Ct. 1991).

as unduly restrictive of expert testimony. Congress chose to rely instead upon the adversarial process to expose the deficiencies of experts' opinions, and entrusted to juries the task of determining which parties' experts deserved credence. *Id.* at 168; *Barefoot v. Estelle*, 463 U.S. 880, 898, 900-02 & n.8 (1983). And, to address the problem of "venal" experts, Congress empowered federal judges in rule 706(a) to appoint neutral experts who could explain the state of scientific understanding respecting the subject at issue.

Proponents of *Frye* have sought to locate it in the entirely different wording of Rules 702 or 703, but those provisions plainly do not embrace it. Rule 702 merely declares that qualified experts can present opinions whenever the situation is a proper one for expert testimony (i.e., whenever the trier of fact would benefit form receiving specialized knowledge); Rule 702 does not empower judges to evaluate the quality of the opinion the expert witness will render or to exclude opinions that have not achieved general acceptance.

Rule 703 relieves experts of the common law stricture of having to base their opinions solely upon data that has been admitted into evidence, and thus enables them to testify on the basis of, e.g., the data in studies done by others. However, such extra-record data may be relied upon without introducing it into evidence only if it is "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." This does not make Rule 703 the *Frye* rule, for two reasons: (1) the "reasonably relied upon" language does not constrain an expert so long as he or she relies upon data that has been admitted into evidence, and (2) often, as here, the data base that the expert relies upon *is* that relied upon generally by scientists in the field. Rule 703 plainly does not empower courts to forbid experts from testifying to the conclusions they have reached from the accepted database simply because their particular conclusions have not themselves attained general acceptance.

3. An additional consideration that militates strongly against the survival of *Frye* is that it would be outcome determinative in state law diversity cases. For example, the evidence that the courts below *would not admit* has been found sufficient *to sustain the plaintiffs' claim* in a Bendectin case litigated under District of Columbia law.

Because Frye is outcome-determinative, this Court's jurisprudence under *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), would doom any effort to sustain it as a judge-made rule that stands independent of the Federal Rules, at least with respect to state law claims. And the *Frye* rule's substantive effect also strengthens the showing that Congress did not incorporate *Frye* into the Federal Rules. For in crafting those rules, Congress took scrupulous care to assure that none would have outcome-determinative effects on state law. Indeed, in three instances where that potential existed, Congress expressly provided that the rule would apply only to federal question suits. If Congress had intended to incorporate *Frye*, it undoubtedly would have made similar provision to protect state law claims.[43]

ARGUMENT

Introduction

This case centers on an evidentiary rule first announced in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). *Frye* was a federal criminal case in which the U.S. Court of Appeals for the D.C. Circuit addressed the admissibility of expert testimony setting forth the results of a "systolic blood pressure deception test," a rudimentary precursor to the modern polygraph. *Id.* at 1013. Exercising its common-law authority to prescribe rules of evidence for federal criminal trials "'in the light of general authority and sound reason,'" *Rosen v. United States*, 245 U.S. 467, 471 (1918) (quoting *Benson v. United States*, 146 U.S. 325, 335 (1892)), the D.C. Circuit announced what has come to be known as the "*Frye* rule" barring evidence derived from novel scientific techniques:

> Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-

[43] We show in Part II that even if *Frye* survives, it was misconstrued by the court below.

> recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.

Id. at 1014.

In the half-century that followed, many federal courts applied the common-law *Frye* rule to determine the admissibility of a variety of novel scientific techniques in criminal trials. Paul C. Giannelli, *The Admissibility of Novel Scientific Evidence:* Frye v. United States, *A Half Century Later*, 80 Colum. L. Rev. 1197, 1199-1200 & nn. 14-16, 1205-06 (1980) (citations omitted) (scrutinized techniques included "voiceprints, neutron activation analysis, gunshot residue tests, bitemark comparisons, sodium pentothal, scanning electronic microscopic analysis, and numerous other forensic techniques"). During that same period, others rejected the rule as overly vague and unduly restrictive in denying juries useful evidence. *See, e.g., id.* at 1206-28; P. Giannelli & E. Imwinkelried, *Scientific Evidence* 13-14 (1986) ("[T]he [*Frye*] general acceptance test has been rejected by an increasing number of courts and attacked by commentators, who have labelled the test 'infamous,' 'a sport,' 'archaic,' and 'antiquated on the day of its pronouncement'"); p. 29 note 59, *infra*. Dean McCormick catalyzed the attack on the *Frye* rule in the first edition of his leading hornbook. C. McCormick, *Handbook of the Law of Evidence* § 171, at 363 (1954) (general acceptance test "is a proper condition upon the court's taking judicial notice of scientific facts, but not a criterion for the admissibility of scientific evidence").

In 1975, Congress enacted the Federal Rules of Evidence. Neither the *Frye* rule nor any other requirement of "general acceptance" appears in the text of the Rules. Nor is there mention of either in the lengthy and public Advisory Committee and congressional proceedings that eventuated in adoption of the Rules. *See* Giannelli, *supra*, at 1229-30.

The federal circuits have disagreed as to whether *Frye* survived the enactment of the Federal Rules of Evidence.[44] The Ninth

[44] Three circuits have said no: *United States v. Jakobetz*, 955 F.2d 786, 794-97 (2d Cir.), *cert. denied*, 61 U.S.L.W. 3257 (1992); *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 955 (3d Cir. 1990); *United States*

Circuit is one of those that has continued to apply *Frye*, and in the instant case it has taken *Frye* far beyond its pre-1975 confines. In this case, it has held *Frye* applicable to *civil* cases — indeed, to civil diversity cases governed by state substantive law whose outcomes will be effectively determined by the exclusion of evidence that the state would regard sufficient to establish the party's claim. This case affords the Court an opportunity to address the current status of *Frye* and, more broadly, to clarify the meaning of critical portions of the Federal Rules of Evidence.

I. THE *FRYE* RULE IS NOT AN AVAILABLE GROUND FOR EXCLUDING SCIENTIFIC EXPERT TESTIMONY UNDER THE FEDERAL RULES OF EVIDENCE

Two arguments have been advanced by proponents of the *Frye* rule to support its continued use. One is that, because the *Frye* rule was never mentioned during the formulation and enactment of the Federal Rules of Evidence, federal judges remain free to apply it as a judge-made rule independent of the Federal Rules of Evidence. The other argument is that one or another of the specific Rules passed by Congress should be construed to contain the *Frye* principle.

Both arguments are refuted by the plain meaning of the Federal Rules of Evidence. We deal first with the contention that the *Frye* rule stands independent of the Federal Rules (Part I-A), for the discussion of that issue establishes statutory guideposts that are also applicable to the contention that *Frye* is hiding camouflaged *in* the Rules (Part I-B). Finally, we address the special problems that are posed because *Frye* is outcome-determinative and, if a federal rule of evidence, would alter the results of state-law diversity actions in ways never intended by Congress.

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v. Baller, 519 F.2d 463, 466 (4th Cir.), *cert. denied*, 423 U.S. 1019 (1975). Six Circuits have said yes: Ninth Circuit decision below; *Christophersen v. Allied Signal Corp.*, 939 F.2d 1106, 1115-16 (5th Cir.) (per curiam) (en banc), *cert. denied*, 112 S. Ct. 1280 (1991); *United States v. Two Bulls*, 918 F.2d 56, 60 & n.7 (8th Cir. 1990), *reh'g granted, vacated*, 925 F.2d 1127 (8th Cir. 1991) (*en banc*); *United States v. Smith*, 869 F.2d 348, 351 (7th Cir. 1989); *United States v. Shorter*, 809 F.2d 54, 59-61 (D.C. Cir.), *cert. denied*, 484 U.S. 817 (1987); *United States v. Metzger*, 778 F.2d 1195, 1203 (6th Cir. 1985), *cert. denied*, 477 U.S. 906 (1986).

A. In Rule 402, Congress Barred Federal Judges From Employing Common-Law Exclusionary Rules That Were Not Authorized or Incorporated by Other Provisions of the Federal Rules of Evidence

1. Text

The contention that *Frye* survives as a judge-made rule for excluding evidence, merely because it existed for half a century prior to enactment of the Rules, cannot be squared with the plain meaning of the statute. Analysis must begin with the text of Fed. R. Evid. 402, which provides:

> **Rule 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible**
>
> All relevant evidence is admissible, except as otherwise provided by [1] the Constitution of the United States, [2] by Act of Congress, [3] by these rules, or [4] by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

(Brackets added). Rule 402 states unambiguously that "*all* relevant evidence is admissible" subject to enumerated exceptions. Conspicuously, this precise list of exceptions does not provide for exclusion rules created by judges through decisional law. To be sure, this Court is accorded power to enlarge the grounds for exclusion, but the means are clearly stated: "by other rules *prescribed* by the Supreme Court *pursuant to statutory authority*."[45] This refers to the rule-making power in 28 U.S.C. § 2072, and assures that the elaborate procedural requirements and congressional oversight of 28 U.S.C. §§ 2071-77 will precede their

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[45] Congress added the italicized words to underscore exactly how the Court must proceed; the prior version of Rule 402 promulgated by the Court had used broader language: "by other rules adopted by the Supreme Court." *See* Note (Federal Judicial Center) to Rule 402. *Federal Rules of Evidence for the United States Courts and Magistrates* 26 (West Publishing Co. 1992). As we show in Part I-C, *infra*, Congress injected this limitation to protect state substantive law against erosion caused by judge-made rules of evidence. Congress's use of the word "prescribed" and insertion of the four words "pursuant to statutory authority" renders frivolous any argument that Rule 402 contemplates the courts' exercise of a common-law power to formulate evidentiary standards.

adoption. *See* Judge Edward R. Becker & Aviva Orenstein, *The Federal Rules of Evidence After Sixteen Years — The Effect of "Plain Meaning" Jurisprudence, the Need for an Advisory Committee on the Rules of Evidence, and Suggestions for Selective Revision of the Rules*, 60 Geo. Wash.L.Rev. 857, 858-62 (1992). This statutory scheme would be wholly undermined if the federal courts had power to create and apply additional exclusion rules through decisional law.

The clarity of Rule 402's command should be the end of the matter. This Court has held that the Federal Rules of Evidence are to be interpreted like any other statute. *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163 (1988) ("[b]ecause the Federal Rules of Evidence are a legislative enactment, we turn to the 'traditional tools of statutory construction,' in order to construe their provisions") (citation omitted). *See also United States v. Rogers*, 918 F.2d 207, 209 (D.C. Cir. 1990) (Thomas, J.) (on evidence questions a court must "begin as . . . with any statute, with the language of the rules themselves").

This Court has repeatedly refused to entertain litigants' policy arguments for altering a straightforward reading of the Rules. For example, in *Huddleston v. United States*, 485 U.S. 681, 687-88 (1988), the Court rejected the theory, *id.* at 685 n.2, that where the prosecution produces evidence of "other crimes" for a noncharacter purpose complying with the plain terms of Rule 404(b), the trial judge should engage in independent scrutiny of whether the other crimes occurred. The Court unanimously held that this theory was "inconsistent with the plain language of Rule 404(b)" which contained "no intimation . . . that any preliminary showing is necessary before such [extrinsic act] evidence may be introduced for a proper purpose." *Id.* at 687-88. *See also United States v. Salerno*, 112 S. Ct. 2503, 2507-08 (1992) (refusing to engraft an "implicit limitation[]" to Rule 804(b)(1) despite claims of government abuse of the Rule); *United States v. Owens*, 484 U.S. 554, 561-62 (1988) (finding Rule 801(d)(1)(C)'s "subject to cross-examination" requirement met by witness' mere presence at trial, despite his loss of memory on the issue in question).[46]

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[46] The *only* circumstances where this Court has declined to apply the plain meaning of the Rules have been those where the result would be arguably unconstitutional or so absurd as to be wholly inconsistent with congressional purpose — canons of construction applicable to legislative interpretation generally. In *Green v. Bock Laundry Machine Co.*, 490 U.S. 504 (1989), this Court found that Fed. R. Evid. 609(a) (concerning impeachment by other crimes), if read literally, would require a weighing of prejudice only against the *defendant* in a civil or criminal case — so that "impeachment detrimental to a civil *plaintiff* always would have to be admitted." *Id.* at 509-10. The Court held that although the imbalance in Rule 609(a) could be justified in the criminal context, the civil context mandated equality between plaintiff and defendant; the Court could not "accept an interpretation that would deny a civil plaintiff the same right to impeach an adversary's testimony that it grants to a civil defendant." *Id.* at 510. *See also id.* at 527 (Scalia, J, concurring in the judgment) ("[w]e are confronted here with a statute which, if interpreted literally, produces an absurd, and perhaps unconstitutional, result," justifying a resort to legislative history "to verify that what seems to us an unthinkable proposition (civil defendants but not civil plaintiffs receive the benefit of weighing prejudice) was indeed unthought-of, and thus to justify a departure from the ordinary meaning of the word 'defendant' in the Rule"); *United States v. Zolin*, 491 U.S. 554, 565-66 (1989) (refusing to read Rules 104(a) and 1101(c), stating that privileges apply in all proceedings, to produce the "absurd result" that the crime-fraud exception to the attorney-client privilege could almost never be proven, because a judge would never have authority to examine relevant documents *in camera*). Receiving scientific expert testimony, if none of the statutory tests governing the evidence is violated, *see* Part I-B, *infra*, does not remotely trigger those exceptions.

Of particular application here, this Court has refused to depart from the plain meaning of the Rules as a means of preserving pre-1975 common-law doctrines inconsistent with language in the Rules. In *Bourjaily v. United States*, 483 U.S. 171 (1987), the Court considered the status of the long-established common-law "bootstrapping rule" under the co-conspirator exception to the hearsay rule. That rule — firmly embraced by the Court itself prior to the Rules' enactment in 1975 — had always barred hearsay statements *themselves* from being used to prove conspiracy and thus to trigger the co-conspirator exception to the prohibition on hearsay. In previous cases, the Court had reasoned that without that rule, "'hearsay would lift itself up by its own bootstraps to the level of competent evidence.'" *Id.* at 177 (citation omitted). In considering whether that rule had survived enactment of the Federal Rules of Evidence, the Court noted Rule 104(a)'s provision that when deciding preliminary facts conditioning the admissibility of evidence, a trial court "is not bound by the rules of evidence except those with respect to privileges." The Court found this plain

language decisive and rejected a contrary argument that the bootstrapping rule should prevail because Congress had not specifically evidenced an intent to discard it:

> [The text of Rule 104(a)] would seem to many to be the end of the matter. Congress has decided that courts may consider hearsay in making these factual determinations.
>
> * * *
>
> [But] [p]etitioner claims that Congress evidenced no desire to disturb the bootstrapping rule, which was embedded in the previous approach, and we should not find that Congress altered the rule without affirmative evidence so indicating. It would be extraordinary to require legislative history to *confirm* the plain meaning of Rule 104.

Id. at 177-78 (emphasis in original).

Bourjaily shows the unsoundness of any contention that rules of exclusion not themselves incorporated into the Federal Rules of Evidence can survive the command of Rule 402. This does not mean, of course, that Congress abandoned all that had gone before. Congress enacted the Federal Rules of Evidence against the backdrop of a long history of common-law development of evidence rules. "Before the present Rules were promulgated, the admissibility of evidence in the federal courts was governed in part by statutes or Rules, and in part by case law." *United States v. Abel*, 469 U.S. 45, 50 (1984). Not surprisingly, Congress chose to incorporate many of these common-law doctrines for excluding evidence into the Rules. However, when it did, it did so explicitly. As the Advisory Committee's Note to Rule 402, ¶ 3, explains, in Article IV and succeeding Rules Congress specifically designated the grounds for excluding or limiting the scope of evidence.

Most of the common-law exclusionary doctrines preserved by the Rules appear in Article IV, entitled "Relevancy and Its Limits." Rules 404 through 412 set out a list of categorical grounds codifying the common-law rules that Congress saw fit to impose as limits on otherwise relevant evidence.[47] Other explicit rules authorizing

[47] As the Advisory Committee's Note states, these statutory exceptions were imposed "in response to the demands of particular policies," that were thought to "require the exclusion of evidence despite its relevancy." Advisory Committee's Note to Rule 402, ¶ 3. These exceptions preserve common-law rules generally barring character evidence to prove conduct but permitting habit evidence (Rules 404 to 406), barring evidence of subsequent remedial measures to prove wrongdoing (Rule 407), barring use of settlement negotiations or payment of medical expenses or existence of insurance to prove liability (Rules 408, 409 and 411), barring use of withdrawn guilty pleas (Rule 410), and generally barring reference to the past sexual behavior of an alleged victim of a sex offense (Rule 412).

exclusion of evidence appear in Rules 501, 704(b), and 801 to 804. In addition to these *per se* exclusion rules, Rule 403 authorizes trial judges to exclude other items of evidence on a case-by-case basis, when a particularistic balancing yields the conclusion that the probative value of the evidence is "substantially outweighed" by danger to the fairness of the trial.

An examination of the text of other provisions of the Federal Rules of Evidence demonstrates that Congress used explicit words when it intended to vest judges with authority to continue to promulgate and apply common-law rules for excluding evidence. Rule 501 states that in federal question cases, *privileges* "shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience."[48] This is the language the federal courts have invoked not only when they are deciding whether to recognize new privileges but also when they are defining the parameters of preexisting common law privileges such as the attorney-client privilege.[49] For example, this Court relied on Rule 501 as

[48] It is noteworthy that Rule 501 does *not* extend federal common-law power to issues involving state-created rights and obligations. *See* Part I-C, *infra*.

[49] Thus, the common-law background can be pertinent to interpreting *ambiguities* in the Rules. *See, e.g., Heckler v. Chaney*, 471 U.S. 821, 832-33 (1985); *Norfolk Redevelopment & Housing Auth. v. Chesapeake & Potomac Tel. Co.*, 464 U.S. 30, 35-36 (1983); *Moragne v. States Marine Lines, Inc.*, 398 U.S. 375, 392 (1970). As the Court explained in *Abel*, endorsing the analysis of Professor Cleary, the Reporter for the Rules:

> "In principle, under the Federal Rules no common law of evidence remains. 'All relevant evidence is admissible, except as otherwise provided . . . .' In reality, of course, the body of common law knowledge continues to exist, though in the somewhat altered form of a source of guidance in the exercise of delegated powers." Cleary, *Preliminary Notes on Reading the Rules of Evidence*, 57 Neb. L. Rev.

authority for its decision in *United States v. Zolin*, 491 U.S. 554, 562 (1989). The language of Rule 501 is striking for its dissimilarity to that in Rule 402 and in the rules specifically addressed to expert opinion (Rules 702 to 706) — none of which contains any authorization for common-law rulemaking. The textual differences become even more significant when the source of Rule 501's language is examined. The "reason and experience" phrase was drawn from the former Fed. R. Crim. P. 26, which had authorized common-law rulemaking with respect to *all* evidence rules in criminal cases. In its Rule 26 form, the language was expansive enough to authorize courts to embrace *Frye* in criminal cases.[50] In shaping the Federal Rules of Evidence, however, Congress opted to carry forward the language *only* with respect to privileges. Nowhere else are the courts left with authority to fashion exclusion rules: everywhere else, rules of exclusion are spelled out explicitly.

908, 915 (1978) (footnote omitted).

469 U.S. at 51-52. For example, in *Abel* the Court unanimously held that the well-recognized ability to impeach for "bias," as the concept is "used in the common law of evidence," could be invoked under the Rules. 469 U.S. at 52. In light of the "state of unanimity" favoring the doctrine under the common law, the Court thought it "unlikely that [the drafters] intended to scuttle entirely the evidentiary availability of cross-examination for bias" — a holding that the Court specifically noted was consistent with Rule 402's requirement that, in general, all relevant evidence is admissible. *Id.* at 50-51.

As *Abel* demonstrates, the wording of Rule 402, creating a presumption of admissibility, obviated any need for Congress to preserve common-law doctrines of *inclusion*, and indeed the Rules do not attempt to do so. By contrast, the plain language of Rule 402 demonstrates that unless Congress preserved or authorized a common-law *exclusion* doctrine in *a specific Rule*, the doctrine cannot be used to exclude evidence.

[50] Federal courts had been creating common-law rules to govern criminal trials "in the light of reason and experience," *Wolfle v. United States*, 281 U.S. 7, 12 (1934), at least since this Court's decision in *Benson v. United States*, 146 U.S. 325, 335 (1892). Congress confirmed this power by incorporating the *Wolfle* language into Fed. R. Crim. P. 26, setting forth common-law authority over criminal evidence law. *Hawkins v. United States*, 358 U.S. 74, 76 (1958). Under Rule 26 as it existed before 1975, federal courts were free to fashion common-law evidence rules for criminal cases as long as they were consistent with the Federal Rules of Criminal Procedure and congressional statutes. *Elkins v. United States*, 364 U.S. 206, 216 (1960).

The intent to limit judicial creativity is further evidenced by the words Congress chose in Article VIII dealing with hearsay. Congress enacted a general ban on hearsay (Rule 802), together with 29 exceptions (Rules 803 and 804). The courts are allowed to fashion additional grounds for exception from the hearsay ban on an *ad hoc* basis in "catchall" provisions, Rules 803(24) and 804(b)(5), but the criteria for exercising that power are spelled out expressly in these rules.[51] The specificity with which Congress allowed some room for judicial creativity in Article VIII underscores again the significance of the total *absence* of any similar language either in Rule 402 (the general provision directing admission of relevant evidence) or in Rules 702 to 706 (the provisions governing expert opinion testimony, *see* Part I-B, *infra*).

In sum, the plain terms of Rule 402 and of Rules 702 through 706 bar any use of judge-made rules for excluding opinion evidence. If Congress had wished to leave room for judicial expansion upon its work, it would have expressly so provided, as it did in Rules 501, 803(24) and 804(b)(5). Under this carefully constructed statutory scheme, there is no judicial power to exclude relevant evidence unless admission of that evidence would violate the Constitution or a specific statutory or Rules provision.[52] If in

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[51] It should be noted that in this instance the exceptions lead to *admission* of evidence, rather than its exclusion, and thus are not in tension with the general preference for admissibility declared in Rule 402. *See* note 49, *supra*.

[52] Indeed, so explicit is the language of Rule 402 that on several occasions the United States has urged this Court — although the Court has not passed on the issue — that Rule 402 not only eliminated common-law rules of evidence, but also "stripped the federal judiciary of its supervisory powers to exclude evidence obtained through gross misconduct by agents of the United States," where that misconduct does not violate the Constitution or a statute. *United States v. Payner*, 447 U.S. 727, 751 n.17 (1980) (Marshall, J., dissenting). The Court in *Payner* held that "the supervisory power does not authorize a federal court to suppress otherwise admissible evidence on the ground that it was seized unlawfully from a third party not before the court"; therefore there was no need to address any conflict between continued use of the supervisory power to exclude evidence and Rule 402. *See also United States v. Caceres*, 440 U.S. 741, 755 & n.22 (1979) (declining to adopt a rule under the supervisory power that would require exclusion of evidence obtained from electronic eavesdropping solely because it violated agency regulations, "without pausing to evaluate the Government's challenge to our power to do

Bourjaily the text of the Rules superseded a common-law doctrine that had been explicitly announced *by this Court* (see pp. 21-22, *supra*), *a fortiori* Rule 402 means that the *Frye* doctrine, which had enjoyed only a mixed reception in the lower federal courts, cannot stand after 1975 as an independent judge-made rule of exclusion.

2. Legislative History

As this Court held in *Bourjaily*, "[i]t would be extraordinary to require legislative history to *confirm* the plain meaning of" a Federal Rule of Evidence. 483 U.S. at 178 (emphasis in original). But even if consulted, the legislative history confirms that Congress meant what it plainly said in Rule 402.

Rule 402 was the key to Congress's goal of creating a coherent, self-contained set of rules ensuring uniformity in federal evidence law. The Senate Report accompanying the bill that became the Federal Rules of Evidence cited the need for "a comprehensive code of evidence . . . to govern the admissibility of proof in all trials before the Federal courts because of the lack of uniformity and clarity in the present law of evidence on the Federal level." S. Rep. No 93-1277, 93rd Cong., 2d Sess. (1974), at [1974] U.S. Code

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so"). *See also* Sara Sun Beale, *Reconsidering Supervisory Power in Criminal Cases: Constitutional and Statutory Limits on the Authority of the Federal Courts*, 84 Colum. L. Rev. 1433, 1488-89 & n.324 (1980) (noting that the Court heard argument twice, but did not decide, a case reviewing a Second Circuit ruling rejecting the Government's reading of Rule 402, *United States v. Jacobs*, 547 F.2d 772, 777 (2d Cir. 1976), *cert. dismissed as improvidently granted*, 436 U.S. 31 (1978)). Judge Bork has expressed the view that Rule 402 *does* preclude exercise of judicial supervisory power except "when specific constitutional or legal provisions call for that remedy." *United States v. Mount*, 757 F.2d 1315, 1322-24 & n.7 (1985) (Bork, J., concurring).

This Court need not, of course, resolve the issue of survival of the Judiciary's supervisory power in this area in order to conclude that Congress plainly meant in Rule 402 to leave no room for judicial application of traditional common-law rules of evidence that were not incorporated into the Rules. Thus, in *Jacobs*, the Second Circuit declined to find that Rule 402 impinged upon the Judiciary's supervisory power, while at the same time recognizing that "[t]he obvious purpose of [Rule 402] was to bar common law rules of evidence or state rules of evidence, if inconsistent" with the Rules. 547 F.2d at 777.

Cong. & Ad. News 7054. Rule 402 is "'the keystone to the whole scheme,'" designed both "to sweep away all pre-existing rules of exclusion" and to "mak[e] clear that the rest of the Evidence Rules are exceptions to the basic rule of relevance." 22 Wright & Graham, *Federal Practice and Procedure: Evidence* § 5192 (1978), at 177 (1978) (hereinafter "Wright & Graham").

Inclusion of a statutory provision that would "wipe the slate clean" had been understood since 1872 to be an obviously essential element of *any* attempt to truly codify evidence law. *See id.* at 178-79 & n.9. *See also* Advisory Committee's Note to Rule 402, ¶ 1 ("The provisions that all relevant evidence is admissible, with certain exceptions, and that evidence which is not relevant is not admissible are 'a presupposition involved in the very conception of a rational system of evidence.' Thayer, *Preliminary Treatise of Evidence* 264 (1898). They constitute the foundation upon which the structure of admission and exclusion rests"). Rule 402 is that provision.

There are clear indications that both the drafters of Rule 402 and the legislators who approved it were aware of the intended effect of Rule 402. The Advisory Committee's Note to Rule 402 is particularly instructive here, given that Congress found Rule 402 "noncontroversial" and did not amend it in any significant way. *See* 22 Wright & Graham, § 5191, at 173-74. Enumerating the sources for exclusionary rules authorized in Rule 402, ¶ 3 of the Note explains that exclusion "may be called for by these rules, by the Rules of Civil and Criminal Procedure, by Bankruptcy Rules, by Act of Congress, or by constitutional considerations." The omission of any reference to *common-law rules* in ¶ 3 cannot be deemed inadvertent, for ¶ 5 specifically refers to "the scope of the common law rules" in addressing a different subject; the drafters were aware of the disjunction between the sources listed in Rule 402 and the common-law rules of evidence.[53] Finally, apart from the Advisory

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[53] Further striking evidence of the Committee's plain intent lies in ¶ 1 of the Note to Rule 402, which indicates that Rule 402 is "similar" to § 351 of the California Evidence Code — a provision that had been adopted for the purpose of "preclud[ing] the possibility that valid restrictions on the admissibility of evidence in addition to those declared by statute will remain.'" 22 Wright & Graham, § 5192, at 179 n.10 (quoting legislative history of Uniform Rule of Evidence 7, which became California Evidence Code § 351).

Committee's Note which was before Congress when it enacted the Rules, congressional hearings put Congress on notice that the plain effect of Rule 402 was to do away with judicially created exclusionary rules.[54]

B. The *Frye* Rule Is Not Contained in or Authorized by the Federal Rules of Evidence

Petitioners have shown that the *Frye* rule cannot stand *independent* of the Federal Rules of Evidence. We now turn to the question whether the *Frye* rule can be found *in* the Federal Rules themselves. The analysis in Part I-A frames the proper approach to answering that question. As we have seen, Congress "wiped the slate clean" by the broad declaration of admissibility in Rule 402, and then inserted specific provisions to preserve those common-law rules of exclusion that it wished to retain.

As a reading of the Federal Rules of Evidence will make plain, there is nothing in the text, anywhere, that remotely resembles the *Frye* rule. Article VII of the Rules deals extensively with the topic "Opinions and Expert Testimony" (containing six discrete provisions dealing with such testimony, in Rules 701 through 706), but the proposition that scientific testimony should not be received unless "generally accepted" is nowhere to be found. The omission is striking, for the *Frye* rule was notorious at the time the Rules were adopted. *See* p. 17, *supra*; *see also* note 57, *infra*. Had the drafters intended to preserve *Frye*, their method makes clear that

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This borrowing is hardly surprising. One of the members of the Advisory Committee had been a drafter of the California code, and to a large extent the Advisory Committee "used the California Evidence Code as a model." *Id.* §§ 5191, at 175; 5199, at 222 & n.16.

[54] After reviewing the legislative record, Professors Wright and Graham reported: "Virtually all of the witnesses in congressional hearings assumed that the effect of adoption of the Federal Rules of Evidence would be to foreclose courts from changing rules of evidence by decision," and "[t]he record strongly suggests that Congress assumed that, except where the Evidence Rules otherwise provide, there would be no decisional law of evidence." 22 Wright & Graham, § 5199, at 222 & n.17.

they would have included it in the text.[55] The omission is not surprising, however, for the Advisory Committee's Notes manifest an intention to broaden the admissibility of expert testimony and to ensure that it would be free of obstacles that had been erected by prior law.[56] This Court has noted the "liberal thrust of the Federal Rules," and in particular how Rules 702 through 705 follow a "general approach of relaxing the traditional barriers to 'opinion' testimony." *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988).[57]

The common-law *Frye* rule operated as a categorical, *per se* bar to admitting scientific evidence that lacked "general acceptance,"

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[55] Indeed, the *Frye* rule is not even mentioned in the Advisory Committee's Notes or the legislative deliberations.

[56] See Advisory Committee's Notes to Rule 702 (expanding expert testimony beyond responses to hypothetical questions; rule is "broadly phrased" to permit admissibility); Rule 703 (overturning the hearsay obstacle to admissibility of expert opinion to "broaden the basis for expert opinions"); Rule 704 (eliminating the objection to admissibility of expert opinion on the "ultimate issue" in the case, thereby facilitating the "basic approach" of the rules to admit expert testimony whenever "helpful to the trier of fact"); Rule 705 (eliminating the "complex and time consuming" hypothetical question rule).

[57] This point has been echoed by leading commentators. As Professor Berger has written, "Wigmore, McCormick, and other eminent commentators . . . complained for decades about common-law restrictions on opinion evidence that deprived triers of fact of valuable information needed for sounder adjudications." Margaret Berger, *United States v. Scop. The Common Law Approach to an Expert's Opinion About a Witness's Credibility Still Does Not Work*, 55 Brooklyn L. Rev. 559, 559 (1989). "As technology advanced and expert testimony became more important in the resolution of increasingly complex litigation, unnecessary impediments became unacceptable," and in particular, "it became clear that the *Frye* rule might block the introduction of important and useful testimony." Judge Jack B. Weinstein, *Improving Expert Testimony*, 20 U. Rich. L. Rev. 473, 476-77 (1986). "[T]the rules reflect an enlightened, academic view of opinion testimony that dates back some fifty years." Judge George C. Pratt, *A Judicial Perspective on Opinion Evidence Under the Federal Rules*, 39 Wash. & Lee L. Rev. 313, 314 & n.5 (1982) (citing authorities). The statutory scheme "rel[ies] heavily on the adversary system," and trusts the ability of counsel to present such testimony and of juries to evaluate it. *Id.* at 313. The goal "[t]hat evidence scholars had long been seeking ha[s] now come to pass." Weinstein, *supra*, at 477.

without further inquiry into the validity of the scientific technique or the possible value of the evidence in a particular case. To find *Frye* preserved in the Rules, then, one would look for a categorical rule of exclusion targeting such evidence, "novel" or otherwise. It is not there. There is only one *per se* exclusionary rule respecting expert opinion evidence, Rule 704(b), and it deals with an entirely different subject, forbidding ultimate expert opinions on the sanity of a criminal defendant. Note, 72 Cornell L. Rev. 620 (1987). No other subject-matter exclusion of expert testimony appears elsewhere in Article VII of the Rules. Nor can any special barrier to scientific evidence be found in the lengthy list of categorical, *per se* grounds for excluding evidence found under Article IV of the Rules, entitled "Relevancy and Its Limits." *See* p. 22, note 47, *supra*.

Despite the lack of an explicit provision excluding testimony about scientific theories that lack general acceptance, some proponents of the *Frye* rule contend that *Frye* has survived, albeit in different words, in Rule 702 or Rule 703.

Rule 702

A plain reading of Rule 702 provides no support for proponents of *Frye*. Rule 702 states:

> **Rule 702. Testimony by Experts**
>
> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

As is apparent from the text of the Rule and the accompanying Advisory Committee's Note, the trial court, when presented with a proffer of expert testimony, must answer two questions:

First, is this a situation in which "specialized knowledge will assist the trier of fact?" In the words of the Advisory Committee's Note to Rule 702, the question is "[w]hether the situation is a proper one for the use of expert testimony," an inquiry that turns on whether "the untrained layman would be qualified to determine intelligently and to the best possible degree the particular issue

without enlightenment from [experts]."[58]

Second, if the jury would benefit from expert testimony, the trial court must then determine whether the witness is "qualified as an expert" in that specialized field. If so, that expert "may testify thereto," that is, concerning specialized knowledge within that field that is pertinent to the issues in dispute.

The argument for finding *Frye* in the words of Rule 702 is that scientific opinion evidence lacking general acceptance should be regarded as testimony that cannot "assist the trier of fact to . . . determine a fact in issue."[59] But this misreads Rule 702. Nothing

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[58] The Advisory Committee's Note repeatedly focuses on the issue of whether "specialized knowledge," as opposed to common knowledge, would benefit the trier of fact. It begins: "An intelligent evaluation of facts is often difficult or impossible without the application of some scientific, technical, or other specialized knowledge." *Id.* ¶ 1. In explaining how a judge is to determine "[w]hether the situation is a proper one for the use of expert testimony," the Advisory Committee Note explains: "There is no more certain test for determining when experts may be used than the common sense inquiry whether the untrained laymen would be qualified to determine intelligently and to the best possible degree the particular issue without enlightenment from those having a specialized understanding of the subject involved in the dispute." *Id.* ¶ 3 (quoting Ladd, *Expert Testimony*, 5 Vand. L. Rev. 414, 418 (1952)).

This explanation is highly instructive. As a key canon for interpreting the Rules, this Court has noted that where "Congress did not amend the Advisory Committee's draft in any way that touches on the question before us, the Committee's commentary is particularly relevant in determining the meaning of the document Congress enacted." *Beech Aircraft*, 488 U.S. at 165 n. 9. Where there is any ambiguity as to "[w]hat was on the Committee's mind," the Court has closely examined the sources cited by the Committee. *Id.* at 165.

[59] *See, e.g., United States v. Christophe*, 833 F.2d 1296, 1299 (9th Cir. 1987) (holding Rule 702 embodies requirement of "appreciable help," which is not met "[u]nless the testimony conforms to a generally accepted explanatory theory," necessary to achieve "the best available approximation of truth in the judgment of the majority of scientists who work in the particular specialty involved"); *United States v. Kozminski*, 821 F.2d 1186, 1194 (6th Cir. 1987), *aff'd in part on other grounds and remanded in part*, 487 U.S. 931 (1988) (setting out "a four-part test" under Rule 702 that goes beyond the "qualified expert" and "proper subject" tests found in the rule, to insist on "conformity to a generally accepted explanatory theory" whose value "outweighs any prejudicial effect"); *United States v. Two Bulls*, 918 F.2d 56, 60 (8th Cir. 1990), *reh'g granted, vacated*, 925 F.2d 1127 (8th Cir. 1991) (*en banc*) (without any statutory analysis, holding that "we feel Rule 702 and *Frye* both require the same general approach to the admissibility of new scientific

in the language of Rule 702 invites the trial court to bar an expert from the stand based on the judge's impression of the value of the expert's opinion. Rule 702 authorizes only a generic inquiry whether "specialized knowledge will assist the trier of fact," and a further inquiry whether the particular witness is "qualified" based on "knowledge, skill, experience, training *or* education" (emphasis added).[60] The function of Rule 702 is to make clear that *if* these requirements are met, the witness may testify "as an expert."[61]

Indeed, the structure of Rule 702 makes clear that the judge can answer these questions *without even knowing what opinion the expert will offer upon assuming the stand* and, thus, without knowing whether the expert's opinion is in the mainstream or on the fringe. For once it is determined that "the situation is a proper one for the use of expert testimony" because "scientific, technical or other specialized knowledge" will assist the trier of fact (*see* p. 30, *supra*) and that the proffered expert is qualified on the subject, then, in the words of Rule 702, the expert "may testify thereto in the form of an opinion or otherwise."[62]

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evidence," in barring "speculative and conjectural testing").

[60] The Advisory Committee Note to Rule 702, ¶ 4, explains that the Rule's definition of a "qualified" expert was intentionally made broad: "the expert is viewed, not in a narrow sense, but as a person qualified [in one of these five ways]." None of these five criteria remotely suggests that only experts holding "generally accepted" views are qualified, and indeed Merrell has regularly conceded in Bendectin trials that plaintiffs' witnesses are qualified within the meaning of Rule 702.

[61] Three other Rules then come into play to permit the trier to benefit from that expert's knowledge: Rules 704 and 705 lift the opinion ban of Rule 701, permitting the witness to testify to the ultimate issue in the case, without a rigid format for disclosing of the underlying facts or data; and Rule 703 lifts the requirement, found in Rules 602 and 701, that a witness testify only from personal knowledge of the facts in the case.

[62] Two other considerations confirm that the reading the proponents of *Frye* attempt to give Rule 702 is misplaced. First, Rule 702 treats equally, and without any distinction, "scientific, technical or other specialized knowledge." But the *Frye* rule by its terms is applicable only to scientific evidence. If the framers had intended to incorporate *Frye* via Rule 702, it is inconceivable that they would have done so without a single linguistic trace of that intention either in the text or the Advisory Committee's Notes. Second, even on the hypothesis that Rule 702 were misinterpreted as authorizing a judge to evaluate the helpfulness of the witness' *particular* opinion, it is preposterous to think

Courts that have carefully analyzed the "specialized knowledge" standard and the Advisory Committee's Note to Rule 702 have held that expert testimony satisfies Rule 702 whenever the issue at stake is not easily ascertainable through the application of common knowledge, and the witness at hand possesses specialized knowledge bearing on that issue.[63]

On the issue of causation in a toxic tort case, common sense dictates that the jury is incapable of making a decision without the benefit of expert testimony, and that the "assist" requirement of Rule 702 has been met. *See, e.g., Christophersen v. Allied Signal Corp.*, 939 F.2d 1106, 1116 (5th Cir.) (Clark, C.J., concurring in the judgment), *cert. denied*, 112 S. Ct. 1280 (1991) (case alleging that worker's occupational exposure to nickel and cadmium triggered colon cancer; "[o]bviously, a medical opinion as to

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that only "generally accepted" views will be helpful to the trier of fact. Science is a field of constant discovery and advance in reasoning, and breakthroughs inevitably take time to gain general acceptance. It is simply not plausible that the drafters would have used the words in Rule 702 (even as misinterpreted by the proponents of *Frye*) if the intention had been to carry forward the *Frye* ban on evidence lacking general acceptance.

[63] *See, e.g., Douglass v. Hustler Magazine, Inc.*, 769 F.2d 1128, 1142 (7th Cir. 1985), *cert. denied*, 475 U.S. 1094 (1986) ("Rule 702 of the Federal Rules of Evidence defines the scope of permissible expert testimony very broadly. The rule and accompanying Advisory Committee Note indicate that such testimony is admissible whenever it concerns a *topic* on which a lay jury would be assisted by such testimony") (emphasis added); *United States v. Onumonu*, 967 F.2d 782, 787 (2d Cir. 1992) (holding under Rule 702 that expert testimony "would have assisted the jury in resolving the only contested issue in the case," because it was "likely that the average New York juror knows little about" subject); *Busby v. City of Orlando*, 931 F.2d 764, 784 (11th Cir. 1991) (overturning district court's exclusion of expert statistical summary because "even the most competent jury could not have" fully understood complex statistics by simple "examination of the original documents," thus finding "assistance to the trier of fact" standard met); *United States v. Rivera Rodriguez*, 808 F.2d 886, 888 (1st Cir. 1986) (quoting Advisory Committee's Note and finding Rule 702 met because it was "doubtful that the jurors could have determined, without the aid of the expert witness," the issue at hand, which was not "within the common knowledge of the juror"; "an appropriate explanation by an expert is preferable to jury speculation"); *Wilder Enterprises v. Allied Artists Pictures*, 632 F.2d 1135, 1143 (4th Cir. 1980) (Rule 702 met because "testimony would help the jury understand the intricacies of film distribution and the nature and effects of splits, subjects which are not common knowledge").

causation would assist the trier of fact in this highly technical scientific case"). The only remaining, necessary determination under Rule 702 is whether the proffered expert is "qualified by knowledge, skill, experience, training, or education" to provide an opinion on that subject. *Frye*'s requirement that the expert's views be "generally accepted" is nowhere in Rule 702.

Indeed, precisely because *Frye* is *not* in Rule 702, those who would like to see district courts have greater control over the admissibility of expert testimony have proposed revisions to Rule 702 to provide it. But, as these efforts to secure revision reflect, the means for securing change from the present Rules' receptivity to expert testimony must be those prescribed in the Rules Enabling Act, not a tortured effort to find *Frye* in the interstices of rules that plainly do not embrace it.[64]

Rule 703

Nor can *Frye* be "found" in Rule 703. Rule 703 provides:

> **Rule 703. Bases of Opinion Testimony**
>
> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

The argument advanced by *Frye* proponents is that the phrase "reasonably relied upon by experts in the particular field in forming opinions" in the second sentence of the rule incorporates the *Frye* rule. This represents a double misreading of Rule 703.

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[64] Moreover, even if the proponents of such a rules change were correct that such a change would be desirable, it would be extremely controversial to make the change applicable to state law diversity actions. As we explain in Part I-C, *infra*, barring expert testimony on the basis of *Frye* can have an enormous substantive effect on state law claims. *See, e.g.*, Judge Jack B. Weinstein, *Rule 702 of the Federal Rules of Evidence is Sound; It Should Not Be Amended*, 138 F.R.D. 631, 636 (1991). Historically, the Rules drafters have shied away from imposing outcome-determinative evidentiary rules upon state law claims, explicitly exempting state law claims from those evidentiary rules that might have that substantive effect. *See* Part I-C, *infra*.

To begin with, Rule 703 provides no textual support for placing special limitations on expert testimony; quite the contrary, its function is to remove burdens imposed by other rules. It does *not* say that experts' opinions, to be admissible, must be affirmatively based on facts and data "reasonably relied upon by experts in the particular field . . . ." It says only that *if* the facts and data are of that character, they "need not be admissible in evidence." Consistent with Rule 703, an expert could rely upon non-hearsay data (for example, symptoms observed during his own physical evaluation of a patient) to formulate an opinion, and that opinion would be admissible whether or not a consensus of the scientific community would rely upon those symptoms to derive an opinion. The expert may do so because the first sentence of Rule 703 explicitly permits an expert to rely, like any *other* witness, on "facts or data . . . perceived by" him or her.

The argument that *Frye* is in Rule 703 also totally misconstrues the second sentence of that rule. The purpose of that sentence, as its literal meaning conveys, is to free experts to testify without having to admit into evidence the data they rely upon for reaching their conclusions.

Rule 703 concerns the "bases" for expert testimony. As the Advisory Committee's Note to Rule 703 indicates, under the common law, an expert could base his opinion on either (1) personal knowledge or (2) assumed facts supported by evidence *in the record*, typically in the form of a hypothetical question. The first sentence of Rule 703 merely preserves this practice, as the Note indicates in ¶ 1. The innovation of the second sentence of Rule 703 is to add a third basis for expert opinion: information learned by an expert outside of the trial, provided that such information is "of a type reasonably relied upon by experts in the particular field." For example, scientists can now predicate an opinion, as Merrell's Dr. Lamm did in his affidavit submitted by Merrell in support of its summary judgment motion, upon "data on birth defects" gathered by others throughout the world. (J.A. 33).

Thus, the purpose of Rule 703 was to expand the "bases" of expert testimony, not to limit the subject matter of the expert testimony. Rule 702 governs the subject matter issue, permitting an expert to convey "specialized knowledge" from a given field; Rule 703 then permits the expert to rely on non-record facts or data — what would otherwise be hearsay — "[i]f of a type reasonably relied

upon by experts in the particular field in forming opinions or inferences upon the subject."

The function of this second sentence has nothing to do with scrutinizing the particular opinions offered by an expert; its sole mission is to remove the requirement of Rule 602 that a witness generally must have "personal knowledge" of the matter he is addressing. The language of Rule 602 confirms this reading of Rule 703. Rule 602 states that its requirement "is subject to the provisions of Rule 703, relating to opinion testimony by expert witnesses." The Advisory Committee's Note to Rule 602, ¶ 3, explains that despite Rule 602, when an expert testifies to specialized knowledge, Rule 703 allows the expert "to express opinions based on facts of which he does not have personal knowledge." Thus this second sentence streamlines the trial process by permitting experts to refer to what colleagues told them about a case, without a need to bring in the witnesses having personal knowledge, thus cutting down on the number of experts needed to provide comprehensive information to a jury.[65]

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[65] The legislative history of Rule 703 confirms its plain language and this characterization, demonstrating that it was designed to permit experts to refer freely to the types of hearsay information routinely referred to in their fields, thus streamlining the trial process, in a manner akin to the "business records exception" to the hearsay rules. The Advisory Committee's Note states that "the rule is designed to broaden the basis for expert opinions beyond that current in many jurisdictions and to bring the judicial practice into line with *the practice of the experts themselves when not in court*." (Emphasis added). Using the example of a diagnosing physician, the Note states that many sources relied upon by experts "are admissible in evidence, but only with the expenditure of substantial time in producing and examining various authenticating witnesses," and concluded that the expert's "validation [of these sources], expertly performed and subject to cross-examination, ought to suffice for judicial purposes."

The lower federal courts have had no difficulty discerning the function of the second sentence of Rule 703. *See, e.g.*, *Ambrosini* v. *Labarraque*, 966 F.2d 1464, 1466 (D.C. Cir. 1992); *DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 953 (3d Cir. 1990); *United States* v. *Unruh*, 855 F.2d 1363, 1376 (9th Cir. 1988), *cert. denied sub nom. Forde* v. *United States*, 488 U.S. 974 (1988); *United States* v. *Kail*, 804 F.2d 441, 447 (8th Cir. 1986); *United States* v. *Wright*, 783 F.2d 1091, 1100 (D.C. Cir. 1986); *First National Bank of Kenosha* v. *United States*, 763 F.2d 891, 895 (7th Cir. 1985); *Mannino* v. *International Manufacturing Co.*, 650 F.2d 846, 851 (6th Cir. 1981).

Moreover, even if the words of Rule 703 *could* be construed as a limit upon the admissibility of expert opinions generally, they do not constitute an adoption of the *Frye* rule. Here, plaintiffs' experts consulted the very facts and data that scientists generally rely upon in formulating an opinion about toxic causation (see p. 4-6, *supra*). What Merrell protests is not the experts' choice of data base, but the conclusions they drew from their analysis of that data. By its terms, Rule 703 has nothing to do with the controversial nature of the expert's conclusion. Rule 703 is a limitation upon the type of *data* to which the expert *applies* his or her thinking process, not a restriction upon the conclusions the expert reaches from that process.[66]

The framers of the Rules in their present form were not oblivious to the danger that there might be scientists or other experts who, for a fee, would testify to highly dubious opinions. The very first words of the Advisory Committee's Note to Rule 706 refer to "[t]he practice of shopping for experts [and] the venality of some experts." The framers' solution, however, was not to exclude controversial testimony *per se*, but to arm the opposition and the district court with procedural tools to strengthen the adversary process and thus to ensure that the trier of fact would receive an accurate picture respecting the state of scientific opinion. Although Rule 705 permits experts to testify without first offering the facts or data to the trier of fact, the Advisory Committee's Note to Rule 705 points to recent changes in discovery procedures designed to ensure advance disclosure of the expert's views to facilitate effective cross-examination.[67] In Rule 803(18), the framers significantly expanded the "learned treatise" exception to the hearsay rule to better enable

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[66] Where the complaint is that an expert is deriving a conclusion from a *data base* that is not generally accepted as reliable, e.g., determining causation from the alignment of the planets, and where the data base is one that is not itself admissible, it is plausible to argue that the data base is one not "reasonably relied upon by experts in the particular field in forming opinions" and thus that testimony as to the opinion is barred by hearsay. But this is a far cry indeed from the Ninth Circuit's use of *Frye* to bar to the admissibility of opinions that *are* derived from the generally accepted data base but that supposedly constitute conclusions that are not "generally accepted."

[67] Fed. R. Civ. P. 26(b)(4). *See, e.g.*, Weinstein, *supra* note 57, at 483-85; Pratt, *supra* note 57, at 322-25.

a cross-examiner to show the trier of fact where an expert departs from the mainstream. *See* Lynne Heckert, "Use of Learned Treatises at Trial," 1984 Trial Lawyer's Guide 165.

Moreover, in Rule 706(a) Congress showed the ultimate choice it made regarding the policy concern that the evidence rules might permit marginal testimony based on extreme positions. Congress addressed that concern *not* by enacting an indiscriminate *Frye*-type categorical rule excluding scientific testimony lacking general acceptance, but rather by empowering district courts to appoint experts of their own choosing to testify as neutral witnesses. The Advisory Committee's Note shows that this power was conferred to deal with the problem of the expert as "hired gun":

> The practice of shopping for experts, the venality of some experts, and the reluctance of many reputable experts to involve themselves in litigation, have been matters of deep concern. Though the contention is made that court appointed experts acquire an aura of infallibility to which they are not entitled, . . . the trend is increasingly to provide for their use. While experience indicates that actual appointment is a relatively infrequent occurrence, the assumption may be made that the availability of the procedure in itself decreases the need for resorting to it. The ever-present possibility that the judge *may* appoint an expert in a given case must inevitably exert a sobering effect on the expert witness of a party and upon the person utilizing his services.

(Emphasis added). There are, of course, some who contend that this arsenal is inadequate. But, as already noted, Rule 402 identifies the means by which additional *per se* rules can be promulgated, and judge-made rules like *Frye* are not among them. *See* pp. 23-26, *supra*.

Finally, it should be noted that Rule 403 empowers district judges to engage in *ad hoc*, case-specific balancing to exclude otherwise admissible evidence (including expert testimony) "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury . . . ." Application of this test in particular cases may result in the exclusion of evidence that the *Frye* rule was designed to block. However, the *per se* quality of the *Frye* rule pretermits this weighing process and removes the discretion from the trial judge without according the testimony the presumption of admissibility

that must be "substantially outweighed" by the particulars of the case."[68]

In sum, the Rules reflect broad hospitability to the receipt of expert testimony, and a reliance upon the ultimate safeguard that this Court identified in *Barefoot v. Estelle*, 463 U.S. 880, 898 (1983):

> [T]he rules of evidence generally extant at the federal . . . level[] anticipate that relevant, unprivileged evidence should be admitted and its weight left to the fact-finder, who would have the benefit of cross examination and contrary evidence by the opposing party.

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[68] In the instant case, for example, the following factors would have to be considered before the plaintiffs' expert testimony could be excluded by a trial court under Rule 403:

(1) To exclude the testimony in this case non-suits the plaintiffs, as it is impossible to prove causation in a toxic tort cause except through expert testimony; thus the prejudice to the plaintiffs is absolute. The usual occasion for invoking Rule 403 is to exclude expert testimony that might confuse the jury, and to allow the jury to rely upon its own common sense instead; that course visits no similar injury upon the party whose expert evidence is excluded.

(2) This is not a case where the evidence is likely to confuse the jury: it is not a case where the jury is to be dazzled by a machine that it cannot understand, but rather one where the jury will know that plaintiffs' experts have drawn conclusions from the traditional data base that conflicts with the conclusions of many other experts who have looked at the same database. *See* pp. 43-44, note 71, *infra*. The testimony here is no more beyond the jury's understanding than is *any* medical evidence in any case.

(3) Neither is this a case where the nature of the disagreement is beyond a jury's comprehension; the debate between the experts described *supra* at pp. 8-12, is quite straightforward.

(4) On its face, the proffered testimony of plaintiffs' witnesses has substantial probative value. Indeed, as the Statement shows, their position on both areas of disagreement with Merrell's experts is both intrinsically substantial and has significant support in the scientific community.

(5) Finally, the district court could exclude this otherwise relevant evidence only upon a finding that its probative value was "substantially outweighed" by its potential to mislead or confuse the jury. As the Third Circuit has opined in another Bendectin case, "Rule 403 is an unlikely basis for exclusion." *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 957 (3d Cir. 1990). *See also Busby v. City of Orlando*, *supra* note 63, 931 F.2d at 784.

In *Barefoot*, which involved the admissibility of psychiatrists' opinions that were challenged by the American Psychiatric Association as heretical,[69] this Court stressed that "the purpose of the jury is to sort out the true testimony from the false, the important matters from the unimportant matters, and, when called upon to do so, to give greater credence to one party's expert witnesses than another's. Such matters occur routinely in the American judicial system, both civil and criminal." *Id.* at 902 (1983) (internal quotation omitted). The Court repeated that emphasis in *Beech Aircraft*, *supra*, noting "the liberal thrust of the Federal Rules" with regard to opinion testimony. 488 U.S. at 169, again affirming that "the ultimate safeguard" in the Federal Rules is "the opponent's right to present evidence tending to contradict or diminish the weight of those conclusions." 488 U.S. at 168.

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[69] *Barefoot* involved a constitutional challenge to the receipt of psychiatric testimony on future dangerousness in a state criminal proceeding. The mainstream of the psychiatric profession believed that psychiatrists' efforts to make such predictions are totally unreliable, a point brought to the Court's attention in an amicus curiae brief of the American Psychiatric Association. Without challenging the accuracy of the APA's headcount, the Court responded:

> If [the four psychiatrists whose testimony was at issue] are so obviously wrong and should be discredited, there should be no insuperable problem in doing so by calling members of the Association [to testify against them.] . . . We are unconvinced, however, at least as of now, that the adversary process cannot be trusted to sort out the reliable from the unreliable evidence . . . .
>
> ***
>
> All of these doubts about the usefulness of psychiatric predictions can be called to the attention of the jury . . . Petitioner's . . . argument . . . is founded on the premise that the jury will not able to separate the wheat from the chaff. We do not share in this low evaluation of the adversary process.

463 U.S. at 900-01 & n.8.

C. The *Frye* Rule Would Often Be Outcome-Determinative in State-Law Diversity Actions. This Precludes Its Application to Diversity Actions As an Independent Judge-Made Rule, And Confirms That Congress Did Not Intend to Incorporate It *Into* the Federal Rules of Evidence

Our demonstration to this point has not taken account of the federalism concerns that flow from the fact that the Federal Rules of Evidence apply to diversity actions governed by state substantive law. Those concerns strongly reinforce the conclusion that *Frye* has not survived the enactment of the Federal Rules, either as an independent judge-made rule or as assimilated into the Rules.

The Federal Rules of Evidence as enacted in 1975 were crafted so as not to alter the substantive law applicable in diversity cases. Early in the drafting process Judge Weinstein warned of the "residual federalism issues" posed by certain categories of rules: burdens of proof, presumptions and rules concerning the competency of witnesses. *See* Weinstein, *The Uniformity-Conformity Dilemma Facing Draftsmen of Federal Rules of Evidence*, 69 Colum. L. Rev. 353, 361, 363-70 (1969). When such concerns were not fully heeded in the original version of the Rules, Congress held up promulgation and engaged in a review and amendment process, largely out of concern about the threat to state interests posed by the Rules. "[T]he Rules were criticized for failing to provide recognition in diversity cases for state rules of evidence that might be thought of as substantive under the *Erie* doctrine," and Congress made specific amendments to the original version of the Rules to decree "an adherence to state law in diversity cases on issues of presumptions [Rule 302], privileges [Rule 501], and competency of witnesses [Rule 601] that many commentators felt was required by the *Erie* case anyway." 22 Wright & Graham, § 5006, at 106, 108. Out of its concern that "state rules that ought to have been considered 'substantive' were overridden in the Court's version," Congress "sought to assure a minimum of tampering with state substantive rights," thus policing "the limitation specified in the second sentence of the 1934 Rules Enabling Act against abridging substantive rights." Olin Guy

Wellborn III, *The Federal Rules of Evidence and the Application of State Law in the Federal Courts*, 55 Tex. L. Rev. 371, 401 (1977).

Given this history, it is inconceivable that Congress meant either to incorporate the *Frye* rule or to leave it intact. Whether *Frye* is conceived to be a common-law doctrine functioning independent of the Rules, or as a test that might plausibly be read into some provision of the Rules, the *Frye* rule applied by the court below inescapably will alter the substantive outcome of state law cases depending upon whether they are tried in federal or state court.

This point can be made most concretely by consideration of the District of Columbia Court of Appeals' decision in *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C. 1986), *cert. denied*, 110 S. Ct. 1121 (1990). There, as here, Merrell argued that plaintiffs could not prove that Bendectin causes limb reductions. On a record substantially similar to that which plaintiffs have proffered here, the D.C. Court of Appeals upheld a jury finding that plaintiffs had met their burden of proving causation. Rejecting Merrell's argument that causation could be established only through an epidemiological study whose results meet the 95 percent confidence level, that court held that causation could be established by the combined effect of analysis of chemical structure, in vivo and in vitro studies, and epidemiological results falling short of the 95 percent confidence level. Whatever the probative effect of any one of those factors standing alone, they "combined to produce a whole that was greater than its parts." 506 A.2d at 110.[70]

If *Frye* is applicable, the next suit brought in the District of Columbia could be removed by Merrell to federal court, and evidence that the D.C. Court of Appeals held sufficient to prove plaintiff's case *would be inadmissible*. It is difficult to conceive a rule that was more outcome-determinative, that would more surely induce forum-shopping, that would more plainly frustrate state or

[70] The *Oxendine* court's reasoning paralleled this Court's in *Bourjaily*, *supra*, 483 U.S. at 179-80 (it is a "simple fact of evidence life" that "individual pieces of evidence, insufficient in themselves to prove a point, may in cumulation prove it. The sum of an evidentiary presentation may be greater than its constituent parts").

local policy governing the bases of substantive tort liability, and that would more lead to unequal administration of the laws (for only those victims who share citizenship with Merrell could have hope of securing the benefits of state law declaring their proof sufficient). In every relevant respect, the rule would be "substantive" within the meaning of *Erie* and its progeny.

It is petitioners' position that, under California law — as under D.C. law — the evidence petitioners have proffered would permit a recovery for petitioners. Clearly, this evidence would be admissible under California law.[71] And while there is no case in

[71] California is one of the states that adopted the *Frye* rule, *see People v. Kelly*, 549 P.2d 1240, 1244 (Cal. Supreme Ct. 1976), but its use has been limited solely to the original context of *Frye — criminal* cases — and California has not followed the Fifth and Ninth Circuits in applying *Frye* to civil cases. Moreover, California has held that a "general acceptance standard may be applied *only* to "the thing from which the deduction is made." *Frye*, 293 F. at 1014. That is, in California criminal cases the *Frye* rule applies only when "the evidence is produced by a machine" or other compelling, non-subjective means, on the theory that "like many laypersons, jurors tend to ascribe an inordinately high degree of certainty to proof derived from an apparently 'scientific' mechanism, instrument or procedure." *People v. McDonald*, 690 P.2d 709, 724 (Cal. Supreme Ct. 1984). *McDonald* therefore held unanimously that *Frye* cannot be used to exclude the conclusions of experts who have studied available data on a particular subject and give their own informed assessment of the data, because such testimony does not raise the concerns addressed by *Frye*. *Ibid.*

The *McDonald* court explained: "When a witness gives his personal opinion on the stand — even if he qualifies as an expert — the jurors may temper their acceptance of his testimony with a healthy skepticism born of their knowledge that all human beings are fallible," and noted that "[w]e have never applied the *Kelly-Frye* rule to expert medical testimony, even when the witness is a psychiatrist and the subject matter is as esoteric as the reconstitution of a past state of mind or the prediction of future dangerousness, or even the diagnosis of an unusual form of mental illness not listed in the diagnostic manual of the American Psychiatric Association *Id.* at 724 (citations omitted). In *People v. Stoll*, 783 P.2d 698, 710-11 (Cal. Supreme Ct. 1989), the California Supreme Court reaffirmed this reasoning and explained that for *Frye* to apply there must be "an unproven technique or procedure [that] appears both in name and description to provide some definitive truth which the expert need only accurately recognize and relay to the jury," such as "machines or procedures which analyze physical data."

Lower court opinions applying *McDonald* make clear that the *Frye* rule could not be applied to exclude petitioners' expert testimony under California

California that has ruled on the substantive issue decided in *Oxendine*, petitioners are prepared to argue below that the California courts would reach the same substantive result as *Oxendine*. Surely, the courts below have not held otherwise; they have not even *looked* at California law. *See* pp. 49-50 n.76, *infra*.

That the *Frye* rule profoundly affects substantive rights has significance for two aspects of this case. First, it wholly vitiates any effort to vindicate *Frye* as a judge-made rule that stands independently of the Federal Rules of Evidence in diversity cases. For, bereft of the sanction of congressional authorization, the *Frye* rule's substantive impact dooms it under *Erie* jurisprudence. *See, e.g.*, *Hanna v. Plumer*, 380 U.S. 460, 469-70, 472 (1965); *Byrd v. Blue Ridge Rural Electric Cooperative, Inc.*, 356 U.S. 525, 536-37 (1958); *Bernhardt v. Polygraphic Co.*, 350 U.S. 198, 202-05 (1956); *Palmer v. Hoffman*, 318 U.S. 109, 117 (1943). See especially *Guaranty Trust Co. v. York*, 326 U.S. 99, 108-110 (1945) (refusing to apply a judicially developed doctrine in the context of diversity litigation in view of the impact of that doctrine on litigant

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law. For example, a California appellate court recently overturned a trial court's use of *Frye* to exclude the opinion of an expert who said that a defendant accused of violent actions had suffered from "confusional arousal syndrome." *People v. Cegers*, 7 Cal.App.4th 988, 995 (Cal. Ct. App. 1992), *review denied*, 1992 Cal. App. LEXIS 4974 (Oct. 1, 1992). Even though the expert's "diagnosis was relatively new to medical science," *Frye* simply did not apply to this "stock medical testimony, subject on cross-examination to probing and on rebuttal to opposition expert evidence," for "[t]his was not a case in which a magical device was unveiled to astound a gullible jury." *Id.* at 304-05. California appellate courts have ruled that expert medical testimony on the cause of an injury cannot be subjected to the *Frye* rule, even where such testimony is novel and unsupported by published scientific studies. *See People v. Pitts*, 223 Cal.App.3d 606, 865 (1990) ("there is a difference between development of a new scientific technique — a novel method of proof — and development of a body of medical knowledge and expertise. . . . The expression of an expert medical opinion as to the cause of a wound or injury falls outside of the realm of what is subject to the *Kelly-Frye* rule") (citation omitted); *McCleery v. City of Bakersfield*, 170 Cal.App.3d 1059, 1071 (1985) (applying *McDonald* rule to admit scientific opinions even though "the proffered testimony in the instant case was novel — the trial court characterized appellants' efforts as 'trying to plow new ground in this case' — and was not backed by extensive scientific literature and scholarly studies as was the proffered testimony in *McDonald*").

and state interests).

Second, the substantive effect of the *Frye* rule in diversity cases also militates strongly against interpreting the Federal Rules of Evidence as incorporating the *Frye* rule. Congress has power to enact preemptive federal tort law that prescribes the quantum of proof required before drug manufacturers are held liable. But there is not the slightest evidence that Congress had any such intention when it enacted the Federal Rules of Evidence. This Court has long held that given the state interests recognized in *Erie* and the Rules of Decision Act, federal statutes and rules should be construed if at all possible to avoid a conflict with those interests. *See, e.g.*, *Hanna*, *supra*, 380 U.S. at 470 (finding an "unavoidable" clash given federal rule of "unmistakable clarity"); *Bernhardt*, *supra*, 350 U.S. at 200-02 (construing federal arbitration statute narrowly to avoid conflict); *Palmer v. Hoffman*, 318 U.S. 109, 117 (1943) (construing Fed. R. Civ. P. 8(c) narrowly to avoid conflict).[72] This practice is in keeping with the general rule of our federal system that Acts of Congress are to be construed "in light of the presumption against the pre-emption of state police power regulations." *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2618 (1992); *see also Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Furthermore, in order for the political safeguards of federalism to function effectively, *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528 (1985); *Gregory v. Ashcroft*, 111 S. Ct. 1069 (1991), the States must be put on notice about how much of their law is being removed by Congress. "Mere silence . . . cannot suffice to establish a clear and manifest purpose to pre-empt local authority." *Wisconsin Public Intervenor v.*

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[72] The force of this policy is vividly illustrated by two unanimous decisions of this Court reaching opposite constructions of the same rule. *Compare Walker v. Armco Steel Corp.*, 446 U.S. 740, 750 (1980) (avoiding construction that, under Fed. R. Civ. P. 3, filing of complaint tolls statute of limitations for state-law actions, where state law requires effectuation of service) *with West v. Conrail*, 481 U.S. 35, 39 & n.4 (1987) (holding that under Rule 3, filing of complaint tolls statute of limitations for federal-law actions, and explaining opposite result in *Walker* as flowing from "[r]espect for the State's substantive decision that actual service is a component of the policies underlying the statute of limitations").

Mortier, 111 S. Ct. 2476, 2483 (1991).

Such an approach is all the more warranted here, for, as we have seen, Congress expressly exempted diversity suits from the scope of those evidence Rules that were thought likely to impact on state substantive law. *See* pp. 41-42, *supra*.[73] Had Congress thought that the Federal Rules of Evidence contained the *Frye* rule, it undoubtedly would have included a similar exemption of diversity suits. The absence of such an exemption is further confirmation that Congress did not believe it was enacting *Frye*.[74]

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[73] Congress was so meticulous in safeguarding federalism values that "[a] study of the enacted Rules reveals little remaining that could plausibly have been attacked, were it subject to the Enabling Act's limitation, as modifying state substantive rights in diversity cases," confirming that Congress was "deeply concerned with preventing the undercutting of state substantive policy." Wellborn, *supra*, 55 Tex. L. Rev. at 401-02 & n.177. That inference follows especially in the context of this products liability suit, for Congress has traditionally been extremely reluctant to interfere with state law in tort cases. *See, e.g., Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984); *see generally* Gottesman, *Draining the Dismal Swamp: The Case for Federal Choice of Law Statutes*, 80 Georgetown L.J. 1, 30-31 (1991).

[74] The framers of the Rules were doubtless aware in 1975 that *Frye* up to then had been exclusively a criminal law evidence doctrine, devised initially under common law and later applied under Fed. R. Crim. P. 26. *See* p. 24 and note 50, *supra*. *Frye* was never applied by a federal appellate court to exclude evidence in a civil case until 1984. *See Barrel of Fun, Inc. v. State Farm Fire & Cas. Co.*, 739 F.2d 1028, 1031 (5th Cir. 1984). To achieve the goal of uniform rules of evidence for criminal and civil cases, *see* Rule 1101(b), the framers were required to choose between writing rules that would bring an end to *Frye* in criminal cases, or rules that would extend *Frye* to civil cases. Construing the Rules as effecting the first option is fully consistent with the "liberal thrust of the Federal Rules" with regard to opinion testimony, *Beech Aircraft*, *supra*, 488 U.S. at 169, and with this Court's *Erie* jurisprudence.

II. EVEN IF *FRYE* SURVIVES, ITS PROPER APPLICATION CANNOT TURN ON WHETHER THE EXPERT'S OPINION HAS BEEN PREVIOUSLY PUBLISHED IN A PEER-REVIEWED JOURNAL

The decision below did not rest with mandating use of *Frye*; it gave *Frye* a new and startling twist. As earlier recounted, plaintiffs' experts here consulted the data sources that scientists customarily rely upon to make findings respecting causation. The use of those data sources surely has "general acceptance" in the field. That is all that the *Frye* rule was ever designed to assure. It excluded testimony when "the thing from which the deduction is made" has not gained general acceptance (there a crude lie detector); so, too, *Frye*'s progeny involved conclusions drawn by experts from new forensic techniques. *See* pp. 16-17, *supra*; note 71, *supra*.

In contrast to such novel techniques, the route by which plaintiffs' experts arrived at their conclusions was through a standard technique in the field — by reanalyzing the epidemiological studies previously conducted by others. The court below did not suggest that such reanalysis is *not* a generally accepted practice in the field; indeed, it implicitly acknowledged that it is (and nothing in the record would support a contrary holding). Instead, the court below construed the *Frye* rule to render the evidence inadmissible because the particular conclusions that plaintiffs' experts derived from that reanalysis of the customary data sources had not been published in a peer-reviewed journal prior to their testifying:

> Plaintiffs argue that reanalysis is a generally accepted scientific technique, so it follows that their experts were basing their opinions on a permissible methodology. But the reanalysis of epidemiological studies is generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field . . . . Plaintiffs' reanalyses do not comply with this standard; they were unpublished, not subject to use in litigation.

J.A. 240-41.

The obligation of publication in such journals, and the concomitant delegation of substantial authority over admission of evidence in federal trials to the private editors of these journals, has no conceivable basis in law. "[T]he Federal Rules of Evidence contain no requirement that an expert's testimony be based upon reasoning subjected to peer-review and published in the professional literature." *DeLuca*, *supra*, 911 F.2d at 954. Indeed, in the vast majority of cases in which experts testify, they proffer opinions about factual issues without having previously published their opinions and without drawing upon the published reasoning of others who have addressed that precise factual issue. Their "peer review" comes when experts called by the other party, or appointed by the Court pursuant to Rule 706, mount the witness stand.

To be sure, that an expert's opinion has not been published in a peer-reviewed journal can be cited by the opposing party as bearing upon its persuasiveness. But the ultimate determination of the persuasiveness of an expert's opinion has been entrusted by the Federal Rules to the jurors, *Barefoot v. Estelle*, *supra*, not the editors of private journals nor even judges who wish to defer to such editors. The peer-review process has many virtues but, as explained in the margin, screening the reliability of experts' views for use in federal court is not among them, for neither the objectives of peer review nor its procedures are suited to the determination of truth.[75]

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[75] The editor-in-chief of the New England Journal of Medicine and a former editor of the Journal of the American Medical Association both have disclaimed that peer review is an appropriate mechanism for determining the truth of experts' opinions. L.A. Times, May 22, 1989, Pt. II, at 3 col. 1 ("[p]eer review is far from being a 'perfect sausage machine for grinding out the truth'" (Dr. Arnold S. Relman); "the peer review process is 'not meant to determine ultimate truth or falsity.' [I]ts main functions [are] 'to improve the quality of what is published' and 'to help editors decide what they want to publish in their journals) (Elizabeth Knoll)). Moreover, the peer-reviewed journals in the fields pertinent to toxic tort causation depend heavily for income upon the advertising of drug companies. Lawrence K. Altman, *Study Says Drug Ads in Medical Journals Frequently Mislead*, N.Y. Times, June 1, 1992, at A1, col. 1 ("In 1991, drug companies spent $351 million on advertisements in medical journals"). The combined effect of all these influences is reflected in a *New York Times*-article which spotlighted a five-year delay in publication of a dissenting "re-analysis" of the efficacy of a frequently prescribed drug, resulting from "academia's surprising aversion to dissent," "the strong ties between scientific journals, academia and the drug industry," and "professional jealousies." *See Hidden Discord Over Right Therapy*, N.Y. Times, Dec. 24, 1991, at B6 col. 1. *See also* Charles W. McCutchen, *Peer Review: Treacherous Servant, Disastrous Master*, Technology Review, Oct. 1991, at 28, 30, 33; Jonathan Schlefer, *Truth, Beauty, and Peer Review*, Technology Review, Oct. 1990, at 5; Lawrence K. Altman, M.D., *The Doctor's World: Peer Review is Challenged*, N.Y. Times, Feb. 25, 1986, at C3 col. 1.

The bizarre "publish or perish" edict for expert testimony issued by the court below is both bad law and bad science, and at least raises ground for constitutional concern. Even if the peculiarly judicial function of deciding on the admissibility of trial evidence could be delegated to a private entity, *cf. Mistretta v. United States*, 488 U.S. 361, 373 n.7 (1989), this effective delegation of decisions on admissibility to private journalists funded in part by parties to litigation hardly safeguards petitioners' right to "an impartial and disinterested tribunal" for decision of their claims. *Joint Anti-Fascist Committee v. McGrath*, 341 U.S. 123, 172 (1951) (Frankfurter, J., concurring). By declining to construe the Federal Rules of Evidence as requiring peer-reviewed publication as the precondition to testimony, this Court can avoid these constitutional concerns in addition to the manifest *Erie* problems. *Siler v. Louisville & Nashville R. Co.*, 213 U.S. 175, 193 (1909).

* * *

Petitioners have demonstrated that the courts below erred by granting summary judgment on the basis that plaintiffs' evidence was rendered inadmissible by the *Frye* rule. Whether there be other grounds for excluding the evidence is a question not addressed below, and one that in the first instance is for the district court. Assuming that the evidence is admissible, the question whether it has sufficient weight to preclude a grant of summary judgment is, in this diversity case, a question of state law; for as shown *supra* pp. 42-44, it is for the state to determine what quantum of proof is needed to establish causation. To this point, neither of the courts below has consulted California law; rather, believing the issue to be one of admissibility of evidence, they have consulted only the decisions of federal courts in other circuits.[76] The determination

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[76] In the words of the district court, it is "unfortunate[] for the plaintiffs" that their position is contrary to the "school[] of thought" "prevailing in the federal courts." (J.A. 229). The court of appeals' analysis begins: "Whether Bendectin is responsible for limb reduction defects is not a new

of state law is also a question for initial consideration by the district court. *Salve Regina College v. Russell*, 111 S. Ct. 1217, 1221-22 (1991).

CONCLUSION

For the reasons stated above, petitioners urge that the judgment below be reversed, and remanded with directions that all remaining questions respecting the summary judgment motion be addressed in the first instance by the district court.

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question in the federal courts" (J.A. 239) and ends by embracing the holdings of other federal circuits. (J.A. 241). Neither opinion cites a single decision of a California court, or recognizes that there is a state law issue to decide.

APPENDIX TO BRIEF OF PETITIONER

STATUTORY AND CONSTITUTIONAL PROVISIONS

FEDERAL RULES OF EVIDENCE

Rule 104. Preliminary Questions

(a) Questions of admissibility generally. Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

(b) Relevancy conditions on fact. When the relevancy of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition.

[Amended effective October 1, 1987]

Rule 401. Definition of "Relevant Evidence"

"Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.

Rule 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible

All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Rule 403. Exclusion of Relevant Evidence on Grounds of Prejudice, Confusion, or Waste of Time

Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

Rule 501. General Rule

Except as otherwise required by the Constitution of the United States or provided by Act of Congress or in rules prescribed by the Supreme Court pursuant to statutory authority, the privilege of a witness, person, government, State, or political subdivision thereof shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and expeience. However, in civil actions and proceedings, with respect to an element of a claim or defense as to which State law supplies the rule of decision, the privilege of a witness, person, government, State, or political subdivision thereof shall be determined in accordance with State law.

Rule 602. Lack of Personal Knowledge

A witness may not testify to a matter unless evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter. Evidence to prove personal knowledge may, but need not, consist of the witness' own testimony. This rule is subject to the provisions of rule 703, relating to opinion testimony by expert witnesses.
[Amended effective October 1, 1987; November 1, 1988.]

Rule 701. Opinion Testimony by Lay Witnesses

If the witness is not testifying as an expert, the witness' testimony in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness and (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue.
[Ammended effective October 1, 1987]

Rule 702. Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Rule 703. Bases of Opinion Testimony by Experts

Tre facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.
[Amended effective October 12, 1984]

Rule 704. Opinion on Ultimate Issue

(a) Except as provided in subdivision (b), testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.

(b) No expert witness testifying with respect to the mental state or condition of a defendant in a criminal case may state an opinion or inferece as to whether the defendant did or did not have the mental state or condition constituting an element of the crime charged or of a defense thereto. Such ultimate issues are matters for the trier of fact alone.
[Amended effective October 12, 1984]

Rule 705. Disclosure of Facts or Data Underlying Expert Opinion

The expert may testify in terms of opinion or inference and gives reasons therefor without prior disclosure of the underlying facts or data, unless the court requires otherwise. The expert may in any event be required to disclose the underlying facts or data on cross-examination.
[Amended effective October 1, 1987]

Rule 706. Court Appointed Experts

(a) Appointment. The court may on its own motion or on the motion of any party enter an order to show cause why expert witnesses should not be appointed, and may request the parties to submit nominations. The court may appoint any expert witnesses agreed upon by the parties, and may appoint witnesses of its own selection. An expert witness shall not be appointed by the court unless the witness consents to act. A witness so appointed shall be informed of the witness' duties by the court in writing, a copy of which shall be filed with the clerk, or at a conference in which the parties shall have opportunity to participate. A witness so appointed shall advise the parties of the witness' findings, if any; the witness' deposition may be taken by any party; and the witness may be called to testify by the court or any party. The witness shall be subject to cross-examination by each party, including a party calling the witness.

(b) Compensation. Expert witnesses so appointed are entitled to reasonable compensation in whatever sum the court may allow. The compensation thus fixed is payable from funds which may be provided by law in criminal cases and civil acions and proceedings involving just compensation under the Fifth Amendment. In other civil cases the compensation shall be paid by the parties in such proportion and at such time as the court directs, and thereafter charged in like manner as other costs.

(c) Disclosure of appointment. In the exercise of its discretion, the court may authorize disclosure to the jury of the fact that the court appointed the expert witness.

(d) Parties' experts of own selection. Nothing in this rule limits the parties in calling expert witnesses of their own selection.
[Amended effective October 1, 1987]

Rule 803. Hearsay Exceptions; Availability of Declarant Immaterial

The following are not excluded by the hearsay rule, even though the declarant is available as a witness:

...

(18) Learned Treatises

To the extent called to the attention of an expert witness upon cross-examination or relied upon by the expert witness in direct examination, statments contained in published treatises, periodicals, or pamphlets on a subject of history , medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. If admitted, the statements may be read into evidence but may not be received as exhibits.

(24) Other Exceptions

A statement not specifically covered by any of the foregoing exceptions but having equivalent circumstantial guarantees of trustworthiness, if the court determines that (A) the statement is offered as evidence of a material fact; (B) the statement is more probative on the point for which it is offered than any other evidence for which the proponent can procure through reasonable efforts; and (C) the general purposes of these rules and the interests of justice will best be served by admission of the statement into evidence. However, a statement may not be admitted under this exception unless the proponent of it makes known to the adverse party sufficiently in advance of the trial or hearing to provide the adverse party with a fair opportunity to prepare to meet it, the proponent's intention to offer the statement and the particulars of it,

including the name and address of the declarant.
[Amended December 12, 1975; amended effective October 1, 1987.]

Rule 804. Hearsay Exceptions; Declarant Unavailable

(b) Hearsay Exceptions.

(5) Other Exceptions

A statement not specifically covered by any of the foregoing exceptions but having equivalent circumstantial guarantees of trustworthiness, if the court determines that (A) the statement is offered as evidence of a material fact; (B) the statement is more probative on the point for which it is offered than any other evidence which the proponent can procure through reasonable efforts; and (C) the general purposes of these rules and the interests of justice will best be served by admission of the statement into evidence. However, a statement may not be admitted under this exception unless the proponent of it makes known to the adverse party sufficiently in advance of the trial or hearing to provide the adverse party with a fair opportunity to prepare to meet it, the proponent's intention to offer the statement and the particulars of it, including the name and address of the declarant.
[Amended December 12, 1975; amended effective October 1, 1987; November 18, 1988.]

OTHER STATUTORY PROVISIONS

28 U.S.C. § 2071 (1988) provides, in relevant part:

§ 2071. Rule-making power generally

(a) The Supreme Court and all courts established by Act of Congress may from time to time prescribe rules for the conduct of their business. Such rules shall be consistent with Acts of Congress and rules of practice and procedure prescribed under section 2072 of this title.

(b) Any rule prescribed by a court, other than the Supreme Court, under subsection (a) shall be prescribed only after giving appropriate public notice and an opportunity for comment. Such rule shall take effect upon the date specified by the prescribing court and shall have such effect on pending proceedings as the prescribing court may order.

28 U.S.C. § 2072 (1988) provides, in relevant part:

§ 2072. Rules of procedure and evidence; power to prescribe.

(a) The Supreme Court shall have the power to prescribe general rules of practice and procedure and rules of evidence for cases in the United States district courts (including proceedings before magistrates thereof) and courts of appeals.

(b) Such rules shall not abridge, enlarge or modify any substantive right. All laws in conflict with such rules shall be of no further force and effect after such rules have taken effect.

The Rules of Decision Act, 28 U.S.C. § 1652 (1988) provides, in relevant part:

§ 1652. State laws as rules of decision.

The laws of the several states, except where the Constitution or treaties of the United States or Acts of Congress otherwise require or provide, shall be regarded as rules of decision in civil actions in the courts of the United States, in cases where they apply.